PART I

ANTI INFLAMMATORY AND ANALGESIC ACTIVITY OF *KARUVILANCHI VER CHOORANAM* (*Smilax zeylanica* Linn.)

&

PART II

DIURETIC ACTIVITY OF *JALAMANJARI CHENDOORAM*

The dissertation Submitted by

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Under the Guidance of

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Dissertation submitted to

THE TAMILNADU DR. MGR MEDICAL UNIVERSITY

CHENNAI-600032

In partial fulfillment of the requirements

for the award of the degree of

DOCTOR OF MEDICINE (SIDDHA)

BRANCH-II-GUNAPADAM

POST GRADUATE DEPARTMENT OF GUNAPADAM

THE GOVERNMENT SIDDHA MEDICAL COLLEGE

CHENNAI – 106.

APRIL 2013

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled "**Anti-inflammatory and Analgesic Activity of *Karuvilanchi ver chooranam (Smilax zeylanica,* Linn)" and "Diuretic Activity of *Jalamanjari Chendooram*"** is submitted to the Tamilnadu Dr.M.G.R.Medical University in partial fulfillment of the requirements for the award of degree of M.D (Siddha) is the bonafide and genuine research work done by **I.Nithyamala** Under my supervision and guidance and the dissertation has not formed the basis for the award of any Degree, Diploma, Associateship, Fellowship or other similar title.

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"Anti-inflammatory and Analgesic Activity of *Karuvilanchi ver chooranam (Smilax zeylanica,* Linn)" and "Diuretic Activity of *Jalamanjari Chendooram*"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. A. Kumar MD (Siddha)**, HOD, Post Graduate Department of Gunapadam, Govt.Siddha Medical College, Arumbakkam, Chennai-106 and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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PRINCIPAL/HEAD OFTHE INSTITUTION

This is to certify that the dissertation entitled **"Anti-inflammatory and Analgesic Activity of *Karuvilanchi ver chooranam (Smilax zeylanica,* Linn)" and "Diuretic Activity of *Jalamanjari Chendooram*"** is a bonafide work carried out by **Dr.I.Nithyamala** under the guidance of **Dr. A. Kumar, M.D (S)**, HOD, Post graduate department of Gunapadam, Govt.Siddha Medical College, Chennai - 106.

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Date: **Date:**

Place: Chennai **Place:** Chennai

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ABBREVIATIONS

WHO	World health organization
OA	Osteoarthritis
HIV	Human immunodeficiency virus
ESR	Erythrocyte sedimentation rate
pH	*Potential of hydrogen*
TLC	Thin layer chromatography
BT	Before treatment
AT	After treatment
KVC	*Karuvilanchi ver chooranam*
OECD	Organization of economical co operative development
L	Lymphocyte
Alb	Albumin
E	Eosinophil
Dep	Deposits
TC	Total count
ESR	Erythrocyte sedimentation rate
OPC	Occasional Pus Cells
OEC	Occasional Epithelial Cells
DC	Differential count
FPC	Few Pus Cells seen
P	Polymorphs
Hb	Haemoglobin
FTIR	Fourier Transform Infrared Spectroscopy
SEM	Scanning Electron Microscope
g.f.r	glomerular filtration rate
SZE	S*milax zeylanica*
IEC	Institutional Ethical Committee
IRB	Institutional Review Board
SZLM	Methanol extract of S*milax zeylanica*
PPT	Precipitate

ACKNOWLEDGEMENT

First of all, I thank my parents and express my whole hearted gratitude to my parents for their valuable support and encouragement from the very beginning.

I would like to acknowledge and extent my heartfelt gratitude to the following persons who have helped me in the completion of this dissertation study.

I offer my deep sense of gratitude to my guide to Prof.**Dr.A.Kumar M.D (S),** Head of the Dept of PG Gunapadam and Research guide in this study, for his valuable guidance throughout the study.

I express my sincere thanks to Principal Prof. **Dr.V.Banumathi M.D. (S),** Govt. Siddha Medical College, Chennai for her permission to perform this study and also for her valuable suggestions and encouragement throughout the course of the study.

I wish to express my heartfelt gratitude to **Dr. V.Velpandian**, **M.D. (S), Ph.D,** Lecturer, Govt Siddha Medical College, Chennai for his valuable guidance, encouragement, good advice and ideas offered during the course of my study.

I wish to express my heartfelt gratitude to **Dr.M.Pitchiah kumar M.D (S),** Lecturer, Govt. Siddha Medical College, and Chennai-106, for his excellent guidance for selection of dissertation drugs, good advice and ideas offered during the course of my study.

I feel intensely grateful to **Dr.S.Ayyasamy, Ph.D,** Assistant lecturer, PG - Gunapadam Department, Govt. Siddha Medical College, Chennai-106 for his encouragement and precious suggestions during the course of my study.

I express my sincere gratitude to Retd. Prof. **Dr.A.Maria Joseph, M.D. (S),** for his excellent guidance in selection of dissertation drugs and valuable suggestions and encouragement throughout the course of the study.

I am thankful to **Dr. Anbu, M.Pharm, Ph.D,** Vel's college of Pharmacy Chennai for helping in the pharmacological study.

I acknowledge my thanks to **Prof.P.Jayaraman Ph.D.**, Director, Plant anatomical research centre, Chennai for their help in doing pharamacognostical studies and other guidance to do the research work. I am also thankful to Mr.E.Manikandan of PARC who helped in the pharamacognostical studies.

I am also thankful to **Dr. Prof. Selvaraj, HOD,** Biochemistry dept, and Lab assistant Mrs. Rajalakshmi, for helping me to carry out the Bio-Chemical analysis studies of the trial drug.

My sincere thanks to **Mrs. Shagila, Research officer**, CRIS, Chennai-106 for doing physico chemical studies.

I convey my thanks to the HOD and staffs of Chemistry and Mechanical engineering departments of **Anna University,** Chennai for their help to do physicochemical studies.

I wish to express my sincere gratitude Prof. **Dr.B. Malarvizhi, M.D. (S),** Head of the Department, Anatomy department, Govt. Siddha Medical College, and Chennai-106, for her excellent guidance for selection of dissertation drugs.

I express my special thanks to **Mrs. Girija Srinivasan,** Assistant Professor in Medicinal Botany, Govt. Siddha Medical College Chennai-106 for her valuable suggestions and help towards the entire Study.

I acknowledge my thanks to **Dr.Sasikala Ethirajulu, M.Sc., Ph.D.**, and **Dr.S.Jegajothi pandiyan,** Assistant Director In-charge, CRIS, Chennai-106, for his help and other guidance to do the research work.

I am also thankful to my college staffs for their kind co-operation for my study.

I extend my gratitude to the animal **Ethical committee members** for their approval to do animal studies in pre clinical studies.

I am also thankful to our Librarian **Mr.V.Dhandayuthapani, B.Com, M.Libsc** and staffs for their kind co-operation for my study.

I extend my gratitude and acknowledgement to The Tamilnadu Dr.M.G.R. Medical University for providing an opportunity to pursue this dissertation study.

I whole heartedly thank **My Patients** for their sincere dedication and co-operation throughout the course of the clinical study.

I should express my gratefulness to all my classmates and PG Gunapaadam students for lending their helping hands whenever needed during the course of the study.

I wish to thank my entire family for providing excellent environment for me. My special thanks to my brother **Thanigaivel** and sister **Isaivani** for taking great efforts in molding my research work.

I dedicate this Dissertation work to my parents **Mr.Indrakumar** and **Mrs.Manjula**, all my teachers and my dear friend Late.**Dr.C.Maria mathi melta B.S.M.S**

1. INTRODUCTION

"Research is to see what everybody else has seen and to think what nobody else has thought"

– Albert Szent-Gyorgyi

(1893-1986, Hungarian biochemist).

Human beings being the cherished persons in this world, enjoy the natural wealth, but are also suffering from innumerable diseases prevailing from time to time. A selected group of people with a great knowledge with super natural powers emerged as *"Siddhars"* who discovered and introduced siddha system of medicine which is a special system for the alleviation of sufferings of human beings from diseases. The Siddhars wrote their knowledge in palm leaf manuscripts, fragments of which were found in different parts of South India.

In siddha system of medicine, the branch of materia medica has been well developed. Purification methods of plants, metals and minerals has been emphasized before starting the actual process of medicines which removes the toxic properties of the elements used in the preparation of medicine.

There are about 2,50,000 to 4,00,000 species of flowering plants existing in the earth. Plants are the major source of therapeutic agents in all the traditional systems of medicine .The earliest use of the medicinal use of plant is found in the 'Rig Veda' written during 4500 B.C to 1600 B.C. Medicinal plants are believed to be an important source of new chemical substances with potential therapeutic effects .Some of the plants has been identified and used in siddha medicines, but many plants require thorough studies for their therapeutic value and clinical usefulness.

WHO support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality;

- ensure the use of safe, effective and quality products and practices, based on available evidence;

- acknowledge traditional medicine as part of primary health care, to increase access to care and preserve knowledge and resources; and
- Ensure patient safety by upgrading the skills and knowledge of traditional medicine providers.

So it is needed to prove the efficacy and safety of our medicines by modern scientific parameters.

Chronic inflammatory diseases remain one of the world's major health problems. Inflammation is the response of living tissues to injury. The clinically useful drug against pain and inflammation exhibit many adverse effects such as non steroidal anti inflammatory drugs [NSAID] causing gastric lesions and also opiates causing tolerance and dependence. Pain is defined as "an unpleasant sensory and emotional experience associated with tissue damage or described in terms of such damage." The conventional drugs used for pain and inflammation are too expensive or toxic and not commonly available to the major people in the world. This leads to great interest in search of safer drug for these conditions.

Siddha system interprets in terms of three elemental theories. The elements of the body are called as 'doshas'. The three humors or doshas namely '*Vatham, Pitham* and *Kabam*', they normally exist in the ratio 1: 1/2:1/4. Derangement of this ratio leads to *Vatha, Pitha* and *Kaba* diseases respectively. One of the major *Vatha* derangements is Keel vayu.

One such disease is *Keelvayu* which is described in the text *'Agasthiyar nadi'*. The types of *Keelvayu* are mentioned in *Noi nadal* part 2 refernces taken from *Sabapathi kaiyedu*, the type *Azhal keelvayu* can be compared with osteoarthritis.

Arthritis describes many conditions that affect the musculoskeletal system. Most of the conditions cause pain, stiffness and swelling of the joints. These symptoms can make the the day to day activities like walking up the stairs, difficult to accomplish.

Osteoarthritis is a form of arthritis that features the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a protein substance that serves as a "cushion" between the bones of the joints. Among the 100 different types of arthritis,

osteoarthritis is the most common form. Before age 45, osteoarthritis occurs more frequently in males. After 55 years of age, it occurs more frequently in females. Osteoarthritis commonly affects the hands, feet, spine, and large weight-bearing joints, such as the hips and knees.

Primary osteoarthritis, osteoarthritis not resulting from injury or disease, is mostly a result of natural aging of the joint. With aging, the water content of the cartilage increases, and the protein makeup of cartilage degenerates. Eventually, cartilage begins to degenerate by flaking. In advanced osteoarthritis, there is a total loss of the cartilage cushion between the bones in the joints. Repetitive use of the worn joints can irritate and inflame the cartilage, causing joint pain and swelling. Loss of the cartilage cushion causes friction between the bones, causing pain and limitation of joint mobility. Inflammation of the cartilage can stimulate new bone outgrowths (osteophytes) to form around the joints. Osteoarthritis occasionally can develop in multiple members in the same family, implying a hereditary (genetic) basis for the condition.

Secondary osteoarthritis is a form of osteoarthritis, caused by another disease or condition. Conditions leading to secondary osteoarthritis include obesity, repeated trauma or surgery to the joint structures, congenital abnormalities in joints, gout, diabetes and other hormone disorders.

Obesity leads to osteoarthritis by increasing the mechanical stress on the joint and consequently on the cartilage. Next to aging, obesity is the important risk factor for osteoarthritis of the knees. Hormonal disturbances, that include diabetes and growth hormone disorders, are also associated with secondary osteoarthritis.

While much has been said about the high incidence of diabetes, HIV and cancer in India, a recent study suggests that osteoarthritis beats them all to claim the No. 1 spot among ailments in India.

OA of the knee is 1 of 5 leading causes of disability among non-institutionalized adults.

About 80% of patients with OA have some degree of movement limitation

& 25% cannot perform major activities of daily living (ADL's), 11% of adults with knee OA need help with personal care and 14% require help with routine needs.

About 40% of adults with knee OA reported their health "poor" or "fair".

- Hip/knee OA ranked high in disability adjusted life years (DALYs) (20) and years lived with disability (YLDs). (20)

There are many internal medicines in siddhha system of medicine, chooranam is one among them, and chooranams are fine dry powders of drugs. The term 'chooranam' may be applied to the powder of a single drug or a mixture of 2 or more drugs, which are powdered separately prior to their being mixed to homogeneity. The chooranam should be as fine as to be called amorphous and should never be damp. The chooranam has a shelf life period of 3 months and should be used with in that period.

As per the literature, '*Vatha nidhanam 800' Karuvilanchi ver chooranam [Smilax zeylanica]* the plant belonging to the family Smilaceae is a drug in siddha system which is the constituent of many *thailam* used for the treatment of *vatha* diseases, and till now the plant has not been scientifically validated for its anti inflammatory and analgesic activity, so I am interested to scientifically validate *Karuvilanchi ver choranam [Smilax zeylanica]* for *Azhal keelvayu* [Osteoarthrirtis] and prove its safety and efficacy pharmacologically as well as in treating the patients.

2. AIM AND OBJECTIVES

Aim:

Herbal medicines have a strong traditional value to be used as drugs in terms of safety and effectiveness for treating different diseases. There are many herbs which are used as rejuvenators as well as for treating disease conditions. Roots of Smilax zeylanica are useful to treat osteoarthritis. The goals of osteoarthritis treatment are to reduce pain and improve joint function. Currently there is no cost effective treatment to meet these goals for a long duration. Hence, my aim is to find a suitable treatment from natural product sources for osteoarthritis.

The ultimate aim of my dissertation work is to prove the **Anti inflammatory & analgesic activity** and safety of ***Karuvilanchi ver chooranam***.

Objective:

The objectives of this dissertation work, is to analyze "***Karuvilanchi ver chooranam***" in the following aspects:

- To collect the literature review
- Get the authentication of the raw drug
- Pharmacognostical study of the raw drug
- Phytochemical and Chemical analysis of the trial drug
- Toxicity study for the safety of the trial drug
- Pharmacological study to evaluate the anti inflammatory & analgesic activity
- Clinical study to assess the efficacy of the drug through open clinical trial in osteoarthritis patients.

3. REVIEW OF LITERATURE

3.1 BOTANICAL ASPECT

Table 3.1 Scientific classification:

SCIENTIFIC NAME:	*Smilax zeylanica* Linn
KINGDOM:	Plantae
PHYLUM:	Magnoliophyta
CLASS:	Angiospermae
ORDER:	Liliales
FAMILY:	Smilaceae
GENUS:	*Smilax*
SPECIES:	*zeylanica*

Vernacular names:

English: Rough bind weed.

Tamil: *Ayadi, Arakkappalai, Arakkappilappi, Aritinpalai, Aritinvayacci, Arkam, Arkappilappu, Arucinavayaci, Civakappalai, Civatacu, Curanacini, Irucu Irucuppalai, Kal Tamarai, Kamalaiyatticuranacini, Kottarkulavi, Kucciratam Kattukodi, Karuvilanchikudam , Malaittamarai, Periyakanni, Payacam, Payaci, Payacu, Payaruti, Payatuti, Peruntamarai, Tirunamappalai, Varkkaputpam*

Sanskrit: *Chopachinee , Vanamadhusnuhi*

Hindi: *Chobchini, Ramdatun, Jangliaushbah*

Kannada: *Kaaduhambu thaavare*

Telugu: *Kummeritheega, Kondadantena, Kondagarbhathige, Konda, Sithapa, Kondathaamara, Kumarabaddu, Kushtaputamara.*

Malayalam: *Cherunchakayagavalli, Kalthamara, Karivilanti.*

Marathi: *Gholbel, Gutwel, Guti;*

Bengali: *Kumarika*

Fig.3.1.1 S*milax zeylanica*

Smilax* - *Genus

A large genus of climbing shrubs distributed in the temperate and tropical regions. About 24 species occur in India.

***Smilax zeylanica* Linn:**

Is a climber with slender 4 – angular branches found throughout the tropical hilly areas from the Himalayas southward to Kerala.

Stem smooth, striate, armed with a few distant prickles.

Leaves alternate, elliptic, lanceolate or ovate, coriaceous, glabrous and used as vegetable.

Flowers in pedunculate many flowered umbels, unisexual;

Fruit globose berry red when ripe;

Roots are eaten for the treatment of venereal diseases and skin troubles and a decoction of the bulbous root is given for sores, swellings and abscesses.

(The Wealth of India)

Uses

- **Roots :**

  Used as a substitute for *sarsaparilla* in the treatment of venereal and skin diseases;

  Decoction is given for sores, swellings and abscesses. Leaves consumed as a vegetable and applied for rheumatism and pain in the lower extremities, used in bloodless dysentery.

- Root also used in diseases of nervous system, epilepsy, psychosis, urinary disorders, polyuria, wasting diseases, Hemiplegia, Parkinsonism, congenital diseases, leprosy and rejuvenator.

- Cakes are made by mixing the root juice with powdered seeds of *Phaseolus mungoand* given with warm milk. Salt is not eaten in day meals.

3.2 SIDDHA ASPECT

பெருமூட்டு வாத குணம்

"வடிவுற்ற பெருமூட்டு வாதம் விதமானது வதுவையே கேளு இனிதாய்
வளமாகவே **இருகால் மூட்டு தன்னில் வீங்கும் வலுதாய் நிமிராதிருக்கும்**
கடிதாகவே பொருந்திடமதினுளைவு வலி களைத்து மிகுதியாகும்
காலுமதிலே நீரு குத்தும் ஊசியைப் போல் கடு குண்டினகம் சுள்ளென
மடியாது குளிரு பனி உடல் உளைவும் சோம்பலும் மாட்டும் இரு கால் தரிப்பும்
மருவியுடல் மெலியுமே நித்திரையதின்றியே மாறாவெ தினம் பெருகி அயரும்
படிநீரிலுறு பேர்கள் அறிய வெகு தெளிவாய் பாடு குறுமுனியினுரையாய்
பகரு தமிழாக இது உலகறிய ஓதினேன் பண்பு தமிழாகவே தான்."

The *'perumootu vatham'* refers to swelling present in both knee joints, inability to move the joint, increasing pain present in the joint, pricking pain in the leg, body pain and laziness present, weight loss, insomnia increases and leads to tiredness.

குக்குடாதி தைலம்

"கருஞ்சூரை வேரினுட தொலி எடு பாவதும் கண்டிடும் ஆதிமூலம்
கருவிலாஞ்சிக்குடம் குக்கில் சதகுப்பையும் கரிஞ்சீரம் சேங்கொட்டையும்
தருமுரிய கடுகுடனே வெள்ளுள்ளி வகைக்கிவை தானாறு கழஞ்செடுத்து
தப்பாமலே ஆவினுட பால்தனிலே அரை தறி துட்டு நீக்கிகோழி
வருமினிய அதினுடைய வயறு தன்னிலே அடை வரிந்து தைத்திறுக்கியதனை
வளமான நின்பினுட பட்டை பலம் அன்பது வை புனலுபடு நூறிலே
பெருமையாய் அனலிடு குறுணியளவாய் இறு பேசு தழுதாழை சாறு
பிலமாகவே அஞ்சுபடியாகவே எடுபேணி எடுபாண்டம் அதிலே.

பக்குவமதாகவே குக்குடம் தன்னையே பாண்டமதில் தூக்கியேதான்
பாகமொடு மூடியே சீலைமண் சுற்றி நீ பார்த்தடுப்பேற்றி வைத்து
ஒக்குமனலே இடு வெந்து பதமாகவே எடு ஒன்றாகவே இடித்து
உறையான நின்பெண்ணெய் இருநாழியே விடு ஊற்று நாரலின் பால் அஞ்சுபடியாய்
சிக்காமலொன்றாய் கலர்ந்திடுப்பேற்றியே சிறக்க அனல் போட்டு கிண்டு
சீராகவே மெழுகானதும் பதம் வடி பரணி சிந்தாதடைத்து வைத்து
தக்கபடி **ஒருவேளை கரண்டியளவே குடி தகுந்த ஈராறு தினமும்**
தவறாத பெருமூட்டு வாதம் திமிரு நீருவலிதான் உளைவு மாறும்".

***Vatha noi nidhanam*- 800**

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Root of karunchoorai,

Karuvilanchikudam (Smilax zeylanica),

Sadhakupai (Anethum graveolens),

Karunjeeragam (Nigella sativa),

Serankottai (Semecarpus anacardium),

Kadugu (Brassica juncea),

Vellulli (Allium sativa),

Each 6 *kazhanju* taken, mixed with cow's milk, then kept inside a hen and stitched, and boiled. Add neem oil and the oil is prepared properly and when taken internally for 12 days cures arthritis of bigger joints and pain.

- The preparations listed below contains *Karuvilanchi* and used in the treatment of *vatha* diseases.

ஊதுவாதம்

- **தைலம்**

"வேந்தனின் தோலும் **கருவிலாஞ்சிகுடம்** விள் நின்பம் எட்டிப்பட்டை
வேகமுறுமே கருங்குறிஞ்சியின் வேரதும் வெவ்வேறாய் இருபலமெடு
……
……
தள்ளாமலே உடல் ஆதி அந்த மிடு தவறாதொறு நாளுமே
தப்பாது சென்னையின் பட்டையோடு நின்ப தொலிதான் புனலிட்டு வந்தால்
மெள்ள உடலில் வேது பண்ணு மிதமே உது மேவும் நாள் தவறாமலே
மேனியணுகாதுடல் நோவு வாத நோவுளைவு மேதினியமுலும் யறியே."

- **சூரணம்**

"கருவிலாஞ்சிகுடம் கொடுவேலி மூலவும் கடுகு மிளகரணை வேரு
கனிவாகவே வகை பலம் நாலதாய் எடு கடிய வெண்நொச்சிவேர் தோல்
……..……..……..…….....
பாங்காக உண்டு வன் பத்தியம் கொள்ளு நீ பகரு புளிமச்சம் தள்ளு
வரும் உடலிலூதுமத வாதகாமாலையும் வரும் சோகை விச பாகவும்
வளர் உடல் விறையல் வலுநோவுளைவு பெருமலும் வலித்துடல் தேறும்."

***Vatha noi nidhanam*- 800** Page no 150

❖ **வாத கோடாரி தைலம்**

‘‘கோதகலவே வாத கோடாரி தைலம் கூறுவேன் கேள்இனி
கொள்ளும் கருங்குறிஞ்சியின் வேரதும் கொடிய வில்லை தோடை முட்டி
போதமுறு வெள்ளாமணக்கு கருநொச்சி வேர் புகலெருக்கு வெண்நொச்சிவேர்
பொருந்தும் கடலாடியோடு எட்டியின் வேரும் புதிய **கருவிலாஞ்சி மூலம்**

.....

.....

கொள்ளும் கரண்டி அளவாக தினமும் இருவேளை கணக்காக ஈராறு நாள் உண்ணுகில்
கூறும் குடல்வாதம் ஆந்திரமுளமாந்தை கும்பவாதமுடன் கரள்வாதம்
விள்ளு திமிரேமவும் பட்சவாதங்களும் வரி குட்டம் சூலையுடனே
வீராம் பௌந்திரம் உள்ளுளைவு அயர்ச்சையும் விட்டிடும் பாதம் வெடிப்பு
தள்ளும் தளர்ச்சைகள் அமஸ்மாரங்களும் தகர் சுழலி அரையாப்பு பிளவை
தப்பாமல் கண்டமாலை படர்தாமரைதான் கிராணி மூலரோகம்
அள்ளும் பிளர்ந்திடும் விப்புருதியானதும் அக்கரம் குடலில் புற்று
அறிய மகோதரம் பெருவயறு காமாலை பீலி ஆன நோய் தீரும்.

***Vatha noi nidhanam*- 800,** Page no 132

Other preparations of Karuvilanchi

❖ ***Ashwa vadham - rasayanam***
***Vatha noi nidhanam*- 800 page no.132**

❖ ***Mangisa vadham – kashayam***
***Vatha noi nidhanam*- 800 page no. 79**

❖ ***Madhusmini – rasayanam***
***Maruthuva aasiriyam* page no.5**

❖ **Ashwagendhi - *rasayanam***
***Maruthuva aasiriyam* page no. 79**

Adjuvant: Hot Water

வெந்நீரின் குணம்:

"வாத குன்ம மறுஞ் **சூலை**
சீத சேத்மஞ் சீறுஞ் சுரம்போங்
காதும் புண்ணுங் கண்ணுந் தீரு
மூதுந் தண்ணீ ருண்ணீ ருண்ணீரே!
மின்னிய வளைக்கை நல்லாய்
மிக்கதோர் வென்னீர் தன்னை
மின்னிய இரவிற் கொள்ள
மலபந்தஞ் சுத்தி யாகுந்
துன்னிய வாத பித்தந்
துரத்திடு மையங் தீர்க்கு
மன்னிய வரோசி கம்போ
மக்கினி தீப மாமே!

- Hot water cures peptic ulcer, **pain**, fever, kapha diseases. When hot water is taken in night it relieves constipation. It also cures vatha, pitham and kabam, induces appetite.

"நெஞ்செரிப்பு நெற்றிகை நீங்காப் புளித்தேப்பம்
வஞ்சமிகும் வாதம் வயிற்றுநோய் - செஞ்சொலாய்
வீழாமல் கட்டு மீறியே காய்ந்தநீ
ராழாக்கு நக்க வறும்."

-Pathartha guna sinthamani

- Boiled water cures regurgitation**, vatha diseases** and diseases of stomach.

"காய்ந்த நீருண்ணுங்கால் கண்செவி நோய் சூலை குன்மம்
தோய்ந்த சுரவேகந் தொடரையம் - பாய்ந்தடரும்
வாதத்தின் கோபமிவை மாறுதமென லாதியருள்
வேதத்தின் வாக்கியமாம் விள்"

- Boiled water also cures eye, ear diseases, pain, fever, kaba diseases, **vatha diseases**, peptic ulcer.

- On the basis of the above literature evidences, after consulting with the staffs and HOD in our department, I have selected hot water as the adjuvant for *Azhal keelvayu* (osteoarthritis) which is one of the vatha diseases.

3.3. SIDDHA ASPECT OF THE DISEASE

Azhal keelvayu

Keelvayu

Synonyms:

Sandhu vali, mootu vali, mega soolai, mudakku vayu, ama vatham.

Definition

Vali kutram afeects the keel or joints and produces disease it is known as *keel vayu.* In the joints signs of inflammation such as swelling, pricking pain, pain, inability to flex the joints, immobile joints will be present; the *iyya kutram* will also increase and produce fever.

Aetiology

In siddha system the aetiology for *keelvayu* is limited within the thridhatu theory. The variation of *vatham* and *kabam* is the main reason for this disease. The derangement occurs under various conditions.

They are

- Physical factors
- Mental factors
- Factor of *pithamegam*
- Factor of *soolai dosham*
- Factor of *ama dosham*

Physical factor:

"வளிதரு காய் கிழங்கு
வரைவிலா தயிலல் கோழை
முளிதயிர் போன் மிகுக்கு
முறையிலா வுண்டி கோடல்
குளிர்தரு வளியிற் றேகங்
குனிப்புற வுலவல் பெண்டிர்
களிதரு முயக்கம் பெற்றோர்
கடிசெயல் கருவிலாமால்"

- *Sabapathi kaiaedu*

- *Ahara and vihara* (errors of diets and habits) that give rise to vatha variation i.e. excessive intake of certain fruits and roots tend to increase *vayu.*

- *Excessive intake of cold substances* or exposure to severe cold , exposure to rain, fog or mist, cold or breeze, staying in high hills all these are liable to increase kabam. On these two essential causes namely vatha and kaba prakobams, *keel vayu* is said to develop.

Further it is said that excessive sexual indulgence that give rise to mega noi (such as Gonorrhea and syphilis) may also produce *keelvayu.*

The causes which produce the 15 kinds of soolai including Mega Soolai are as follows:

"சார்வான சூலை வருமாறு கேளாய்
தக்க சிறைபட்டிருக்கும் தீமையாலும்
ஆர்வான வறச்சுடு சோறருந்தாலும்
அறவுமே சலிப்பாயும் ஓடலாலும்
தார்வான சபை மிகுந்த சண்டையாலும்
தகைவான துவர்பொசிப்பு புகைத்தலாலும்
வோர்வான மோகத்தின் புணர்ச்சியாலும்
மிகுந்தபசி யுறுதலினாலும் சூலையாமே"

Suffering in the jail for a long time, eating dry hot foods, excessive running and fighting, excessive intake of astringents, smoking tobacco, excessive cohabitation and excessive appetite are the main causes for Soolai.

Mental Factors:

"ஆமென்ற வண்ணத்துக் கிறுதி பண்ணி
யுகதி பரதேசிகளை யடித்த பேர்க்கும்
காமென்ற கற்புடைய மங்கை மாரைக்
கருதியே மனத்துளிச்சித்த பேர்க்கும்
வாமென்ற வாழ்மரத்தை வெட்டினோர்க்கும்
வழிமறித்து பொருள் பறித்து மதிகேடர்க்கும்
ஏமென்ற எச்சில் தனைக் கவர்ந்த பேர்க்கும்
இகத்திலே நோவெய்திச் சூலையாமே"

Apart from the physical factors, some other mental factors caused the derangement of *Gunas.* The deranged *Gunas* tend to vitiate the *doshas* and produce the disease.

Those who sent out the beggars without helping them, those who have sexual desire over well characterized ladies, those who cut down the useful trees and those rob from passerby; these people are amenable to get this disease.

Factor of *pithamegam*

According to *Agasthiyar vaidhya kandam – 600 'pitha megam'* is said as an important factor for the causation of *Mega Soolai.*

"ஆச்சிந்த மேகத்தால் கபால சூடாம்
அடங்காத பீனசத்தி லெட்டு வாய்வு
மூச்சிந்த காசத்தி லாறுவாய்வு
மூலதித லபான வரை மூலமாறு
வாச்சிந்த வகையான நோய்களெல்லாம்
வளமீறு மேகமே நோய்களுக்கு ராஜன்
நாச்சிந்த மேகத்தால் சூலைபதி னெட்டும்
நடத்துகிற வித்தையெல்லாம் நவிலுகிறோமே

நவிலக்கேள் மேகத்தால் பித்தமாறும்
நன்றாச்சு ஆரோசியங்கள் வேர்வை தாகம்
நவ்லக்கேள் ஆமமொடு பித்தமையம்
நடப்பின்றி பிரிபிரித்து கமலம் போலாம்
நவிலக்கேள் கூடுவிட்டு கூடு பாயும்
நாமறிக்கும் மேகத்தால் பித்த மீறில்
நவிலக்கேள் சிரசுமுத லபானன் வரைவெந்து
நாகனென்ற கூர்மனோடு அபானன் கேளே."

அபானனென்ற தேவத்ததன்தனஞ் செயனோடு
வரிவளிக்கும் வியானனொடு சமானன் கிரிகரனாம்
வபானன்என்ற பிராணனோடு வாய்வு பத்தும்
வரும்கா றாசா வால்பின் செல்வார்கள்
கபானென்ற யிந்திரியம் வெந்துபோனால்
கலக்கிய தினத்தில் பாசிபற்றுப் போலேதேக
மபானனென்ற அறிவுகெட்டு சூலை ரோக
மதிபோன்ற தேகமதை யழிக்கும் பாரே"

In the above stanzas it is said that *'Megam'* is the chief cause for all diseases especially for 8 types of *peenisms*, 6 types of *kasams* and 6 types of *moolams.* By this Megam, Megasoolai also occur. In this condition the coordination of *vatha, pitha* and *kaba* has been broken down. *Megam* increases *pitha* and so excessive heat is felt from head to *apanan.*

Factor of *ama dosham*

Amam has been defined as a condition in which the first *dhatu* namely *Rasam* is not properly formed due to lowered strength of ushna (agni). According to some, due to the impairment of Agni, the *annasaram* is not properly formed in the amasayam and it is known as *amam.*

When there is impairment of *agni*, proper transformation of the nutrient substances into their respective tissue elements does not take place.

This primary offending factor *ama* after provoking the *'vatha'* travels through subtle channels in the body and settles in the joint where in *Santhitha kaba* resides and antagonizes the functions of *vatha* and *kaba* resulting in pain, swelling and tenderness, restricted movements, malaise , anorexia, fever, constipation or diarrhoea at times.

Classification of *keelvayu:*

It is classified into ten types on thridoshic basis.

They are,

1. *Vali keel vayu*
2. *Azhal keel vayu*
3. *Iyya keel vayu*
4. *Vali Azhal keel vayu*
5. *Vali Iyya keel vayu*
6. *Azhal Vali keel vayu*
7. *Azhal Iyya keel vayu*
8. *Iyya vali keel vayu*
9. *Iyya Azhal keel vayu*
10. *Mukkutra keel vayu*

Signs and symptoms:

Prodroma:

Before the disease starts, first there will be blocking of the nostrils, watering of the nose, hoarseness of voice, light fever, pain in the extremities, stabbing and excruciating pain in the affected joints. These are the prodromal symptoms which will be present.

Symptoms of *Azhal keelvayu:*

"பித்தக்கீல் வாய்வு தன்னாற்
யிறங்கு கீல் மூட்டு வீங்கிச்
சித்தர்செய் மருத்து வத்துஞ்
சீர்படாத் தன்மைத் தாகித்
தத்தறு காய்ச்சல் கண்டு
சாலவே தனைதான் தந்தே
மெத்தறு சிகிச்சை தன்னால்
மென்மேலும் நீங்குமப்பா"

- *Sabapathi kaiaedu*

When vayu is in vitiated condition if diets which stimulate the pitha are taken, pitha keel vayu occurs. In this disease the swelling of the joint increases day by day. As pitha increases kaba in the joint decreases and hence dryness occurs. So durig flexation of the joint crepitus sound is produced. Sometimes stiffness of the joints occurs and the movements become restricted.

Naadi nadai

- *Valiiyya kalappu*
- *Iyyavali kalappu*
- *Vali naadi thanithu miguthiyathal*
- *Valiazhal kalappu*
- *Iyyaazhal kalappu*

3.4. MODERN ASPECT OF THE DISEASE

Osteoarthritis

Osteoarthritis, also called degenerative joint disease, is the most common type of joint disease and is one of the most disabling conditions in developed nations. It is characterized by the progressive erosion of articular cartilage. The term osteoarthritis implies an inflammatory disease. Although inflammatory cells are present, osteoarthritis is considered to be an intrinsic disease of articular cartilage in which biochemical and metabolic alterations result in its break down.

In the majority of instances, osteoarthritis appears insidiously, without apparent initiating cause, as an aging phenomenon (idiopathic or primary osteoarthritis). In these cases, the disease usually affects few joints (oligoarticular) but may be generalized. In about 5% of cases, osteoarthritis may appear in younger individuals having some pre disposing condition, such as previous macro traumatic or repeated micro traumatic injuries to a joint, a congenital developmental deformity of a joint(s), or some underlying systemic diseases such as diabetes, ochronosis, hemochromatosis, or marked obesity. In these settings, the disease is called secondary osteoarthritis and often involves one or several pre disposed joints. Gender has some influence on distribution. The knees and hands are more commonly affected in women and the hip in men.

Pathogenesis

Articular cartilage is the major target of degenerative changes in osteoarthritis. Normal articular cartilage is strategically located at the ends of bones to perform 2 functions:

(1) Bathed in synofial fluid, it ensures virtually friction – free movements within the joint; and

(2) In weight bearing joints, it spreads the load across the joint surface in a manner that allows the underlying bones to absorb shock and weight without being crushed. These functions require the cartilage to be elastic and for it to have unusually high tensile strength.

These attributes are provided by the two major components of the cartilage:

- A special type of collagen (type II) and

- ❖ Proteoglycans, both secreted by chondrocytes.

As is the case with adult bones, articular cartilage is not static; it undergoes turn over in which "worn out" matrix components are degraded and replaced. This balance is maintained by chondrocytes, which not only synthesize the matrix but also secrete matrix-degrading enzymes. Thus the health of the chondrocytes and their ability to maintain the essential properties of the cartilage matrix determine joint integrity. In osteo arthritis this process is disturbed by a variety of influences.

The most important of these influences are aging and mechanical effects. Although osteoarthritis is not exclusively a wear-and-tear process, there is little doubt that mechanical stresses on the joint play a major role in its development. Evidence for this includes the increasing frequency of osteoarthritis with advancing age; its occurrence in weight bearing joints; and an increase in the frequency of the disease in conditions that predispose the joints to abnormal mechanical stresses, such as obesity and previous joint deformity.

Genetic factors also appear to play a role in susceptibility to osteoarthritis, particularly in cases involving the hands and hips. The specific gene or genes responsible for this have identified, although linkage to chromosomes 2 and11 has been suggested in some cases. The risk of osteoarthritis is increased in direct proportion to bone density and high levels of estrogens have also been associated with increased risk of the disease. The overall role played by hormones in the pathogenesis of osteoarthritis remains unclear.

Osteoarthritis is characterized by significant changes in both the composition and the mechanical properties of cartilage. Early in the course of the disease, the degenerating cartilage contains increased water and a decreased concentration of proteoglycans compared with healthy cartilage. In addition there appears to be a weakening of the collagen network, presumably caused by decreased local synthesis of type II collagen, and increased breakdown of preexisting collagen. The levels of certain molecular messengers, including IL–1, TNF and nitric oxide, are increased in osteoarthritic cartilage and appear to be responsible for some of the changes in the composition of the cartilage. Apoptosis is also increased, likely responsible for a decrease in the number of functional chondrocytes. In aggregate, these changes tend to reduce the tensile strength and the resilence of the articular cartilatge. In response to these regressive changes,

chondrocytes in the deeper layers proliferate and attempt to “repair” the damage by producing new collagen and proteoglycans. Although theses reparative changes are initially able to keep pace with the deterioration of cartilage, molecular signals causing chondrocyte loss and changes in the extracellular matrix eventually predominate. Factors responsible for this shift from a reparative to a predominantly degenerative picture remain poorly understood.

Morphology

In the early stages of osteoarthritis, the chondrocytes proliferate. This process is accompanied by biochemical changes as the water content of the matrix increases and the concentration of proteoglycans decreases. Subsequently, vertical and horizontal fibrillation and cracking of the matrix occur as the superficial layers of the cartilage are degraded. Gross examination at this stage reveals a granular articular surface that is softer than normal.Eventually, full thickness portion of the cartilage are sloughed, and the exposed subchondral bone plate becomes the new articular surface. Friction smoothes and burnishes the exposed bone, giving it the appearance of polished ivory (bone eburnation). Concurrently there is rebuttressing and sclerosis of the cancellous bone. Small fractures through the articulating bone are common, and the dislodged pieces of cartilage and subchondral bone tumble into the joint, forming loose bodies (joint mice). The fracture gaps allow synofial fluid to be forced into the subchondral regions in a one-way, ball-valve-like mechanism. The loculated fluid collection increases in size, forming fibrous walled cysts. Mushroom-shaped osteophytes develop at the margins of the articular surface and are capped by fibro cartilage and hyaline cartilage that gradually ossify. The synovium shows minor alterations in comparison to the destruction of the articular surface and is congested and fibrotic and may have scattered chronic inflammatory cells. In severe disease, a fibrous synovial pannus covers the peripheral portions of the articular surface.

Clinical course

Osteoarthritis is an insidious disease. Patients with primary disease are usually asymptomatic until they are in fifties. If a young patient has significant manifestations of osteoarthritis, a search for some under lying cause should be made.

Characteristic symptoms

Characteristic symptoms include

Deep, achy pain that worsens with use;

Morning stiffness;

Crepitus; and

Limitation of range of movement.

Impingement on spinal foramina by osteophytes results in cervical and lumbar nerve root compression with radicular pain,

Muscle spasms,

Muscle atrophy, and

Neurologic deficits.

Typically, only one or a few joints involved, except in the uncommon generalized variant. The joints commonly involved include the hips, knees,lower lumbar and cervical vertebrae, proximal and distal interphalangeal joints of the fingers, first carpometacarpal joints, and first tarsometatarsal joints of the feet. Characteristic in women, but not in men, are *Heberden nodes* in the fingers, representing prominent osteophytes at the distal interphalangeal joints. The wrists, elbows and shoulders are usually spared.

There are still no satisfactory means of preventing primary osteoarthritis, and there are no methods for halting its progression. The disease may stabilize for years at any stage but more often is slowly progressive over the remaining years of life; osteoarthritis is second only to cardiovascular diseases in causing long-term disability.

Investigations:

Laboratory features include the ESR, tests for rheumatoid factor, serum uric acid concentration, and appropriate analysis of synovial fluid along with radiography.

3.5. LATERAL RESEARCH

1. "**Antiulcer activity of *Smilax zeylanica* linn.**"

SP Rao, D Pradhan,

Impact: Planta Activa, Vol. 2012, Article ID

In present study antiulcer activity of hydroalcoholic extract of *Smilax zeylanica* (SZE) roots was investigated in animal model of ulcer. Ulcer was induced by pylorus ligation and pylorus ligation with aspirin. SZE produced significant reductive effect on ulcer at 100, 200 and 400 mg/kg. Efficacy was assessed on the basis of total gastric volume, pH, total acidity, free acidity, and ulcer index and percentage protection. It was observed that SZE significantly ($P<0.05$) reduced level of all parameters assessed in present investigation. From this study it can be concluded that hydroalcoholic extract of roots of *Smilax zeylanica* possess significant antiulcer activity.

2. Pesticidal activity of *Smilax zeylanica* L. extracts on Cryptolestes pusillus (Schon.) (Coleoptera: Cucujidae)

MA Bari, W Islam, AR Khan

Journal of Bangladesh Academy of Sciences, Vol. 34, No. 2, 201-203, 2010

The chloroform and methanolic extracts of *Smilax zeylanica* L. were assessed for mortality against the adults of flat grain beetle, *Cryptolestes pusillus* (Schon.) under laboratory conditions by the surface film method. The methanolic extracts caused significantly high ($p < 0.001$) mortalities than the chloroform extracts. Results obtained show the potential of using *S. zeylanica* extracts for *C. pusillus* management.

3. Evaluation of antioxidant potential of *Smilax zeylanica* L in reversing haloperidol induced catalepsy in rats.

Rasheed ahmed S *et al.*

International journal of pharmacy and pharmaceutical sciences, vol 4, suppl 3, 2012.

4. In- Vitro and In-Vivo Antioxidant Activity Studies on the Leaves *of Smilax zeylanica* L. (Smilacaceae)

Anita Murali et al.

Journal of Pharmacy Research, Vol 3, No 10 (2010)

In the present study, in vitro and in vivo antioxidant studies were performed on the leaves of *Smilax zeylanica* L. Methanol and aqueous extracts of the drug were evaluated for in vitro antioxidant activity using DPPH, hydrogen peroxide, ABTS, nitric oxide and superoxide free radicals. The plant extracts exhibited dose dependent

scavenging effects against the different free radicals tested. The methanol extract (SZLM) was subjected to in vivo antioxidant activity studies using CCl4 induced hepatotoxicity model in Wistar albino rats. The extract (SZLM) exhibited significant increase in the levels of glutathione, tissue proteins and enzymes viz. SOD, catalase and peroxidase at different dose levels. The extent of lipid peroxidation was significantly reduced in the extract treated groups. Results were comparable with that of standard antioxidant silymarin.

5. Antidiabetic activity of methanolic extract of *Smilax zeylanica* Linn in streptozotocin induced diabetic rats

Rajesh, V.; Perumal, P.; Sundarrajan, T.

Internet Journal of Endocrinology; 2010, Vol. 6 Issue 1, p2

6. In-Vitro Evaluation of *Smilax Zeylanica* Linn. Leaves for Anthelmintic Activity

V. Rajesh *et al.*

The Internet Journal of Pharmacology, 2010 Volume 9 Number 1. DOI: 10.5580/797

The objective of the present study was to evaluate the *in-vitro* anthelmintic property of various solvent extracts of *Smilax zeylanica* leaves against *Pheritima posthuma*. Various concentrations of Petroleum ether, Benzene, Chloroform and Methanol extract (20mg/ml and 40mg/ml) were used in evaluation. The activity was assessed by the determination of time of paralysis and time of death of worms. Albendazole (20mg/ml) was included as a reference standard. All the extracts were found to paralyze and kill the worms. The Petroleum ether extract and Chloroform extract showed a potent anthelmintic activity compared to standard drug albendazole. Benzene extract was less potent to cause paralysis and death at 20mg/ml and 40mg/ml, which took more time to paralyze and death. Methanol extract was less potent to cause paralysis at 20mg/ml and 40mg/ml, but caused death of worms earlier than albendazole. It is concluded that the anthelmintic efficacy of solvents extracts of *Smilax zeylanica* might be attributed to the presence of phytochemicals.

7. Anti epileptic activity of alcohol and aqueous extracts of roots and rhizomes of *Smilax zeylanica*

V.Madhavan *et al.*

Pharmacologyonline

4. MATERIALS AND METHODS

4.1. PREPARATION OF *CHOORANAM*:

Material:

Roots of *Smilax zeylanica (Karuvilanchi ver)* 8kg of Fresh roots were taken, and then it was shade dried after that the net weight of the roots were around 1.5 kg.

Collection and Authendication of the materials:

The plant material used in this study was collected during the month of June (2012) from Kanyakumari Dist, Tamilnadu, India and authenticated from the Gunapadam experts in, Govt. siddha medical college, Chennai-106 and Certified from Botanist, Central Research Institute For Siddha, Arumbakkam, Chennai-106.

Purification of the Raw Drug:

The plant roots were well rinsed in water to remove the impurities. Then the roots were cut into pieces and dried in shade.

Preparation of the *chooranam*:

The well dried *Smilax zeylanica (Karuvilanchi ver)* were made into fine powder. The finest physical form of this drug was obtained when the powdered material is sieved through a white cotton cloth *(Vashthirakayam)*.

Purification of *chooranam*:

The *Chooranam* was moistened with cow's milk. The pot was half filled with milk and water. The mouth of the pot was covered and tied with white cotton cloth. The *Chooranam* (moistened by milk) was placed above the tied cloth. The mouth of the pot was closed with another mud pot. The gap between the two mud pots was tied using a wet cloth to avoid evaporation. Then this arrangement was kept on fire and boiled until water level gets reduced in the lower pot. Then the powder was taken, dried, powdered finely and preserved for usage.

Preservation:

The purified *Chooranam* was stored in a clean, air tight glass container. Since the shelflife period of the *Chooranam* is only three months, the prepared *Chooranam* must be used within 3 months period.

Administration of the drug:

Form of the medicine	: *Chooranam*
Route of Administration	: Enteral
Dose	: 1gm
Anubanam (Vehicle)	: Warm water
Times of Administration	: Two times a day; after food
Duration	: 7 weeks

Fig.4.1.1 Dry root of *Smilax zeylanica*

Fig 4.1.2 *Karuvilanchi ver chooranam*

4.2. STANDARDIZATION OF THE DRUG

4.2.1. PHARMACOGNOSTIC ASPECT:

Collection and authentication of the materials:

Plant specimen for the proposed study were collected from Kanyakumari Dist and identified and authenticated by the Gunapadam experts in Department of P.G. Gunapadam, Govt. Siddha medical college, Chennai – 106 and certified by Botanist, Central Research Institute for Siddha, Chennai – 106. Care was taken to select healthy plants and normal roots.

Staining:

The required samples of the root were cut and removed from the plant and fixed in FAAsolution (70% ethyl alcohol, formalin and acetic acid in the ratio of 90 ml: 5 ml: 5 ml). After 24 hrs of fixing, the specimens were dehydrated with graded series of Tertiary –Butyl alcohol as per the schedule given by Sass, 1940. Infiltration of the specimens was carried by gradual addition of paraffin wax (melting point 58-60 C) until TBA solution attained super saturation. The specimens were cast into paraffin blocks.

Sectioning

The paraffin embedded specimens were sectioned with the help of Rotary Microtome. The thickness of the sections was 10-12 μm. Dewaxing of the sections was by customary procedure (Johansen, 1940). The sections were stained with **Toluidine blue** as per the method published by O'Brien et al. (1964). Since **Toluidine blue** is a polychromatic stain. The staining results were remarkably good; and some **cytochemical** reactions were also obtained. The dye rendered pink colour to the **cellulose** walls, blue to the **lignified** cells, dark green to suberin, violet to the mucilage, blue to the **protein** bodies etc.

Photomicrographs

Photographs of different magnifications were taken with **Nikon lab photo 2** microscopic Unit. For normal observations **bright field** was used. For the study of **crystals, starch grains** and **lignified** cells, **polarized** light was employed. Since these structures have **birefringent property**, under polarized light they appear bright against dark background. Magnifications of the figures are indicated by the scale-bars. Descriptive terms of the anatomical features are as given in the standard Anatomy books (Esau, 1964).

4.2.2. PHYSICO-CHEMICAL ANALYSIS:

Procedures:

Total ash

Two grams of grounded air-dried material was accurately weighed in a previously ignited and tared silica crucible. The drug was gradually ignited by raising the temperature to 450°C until it was white. The sample was cooled in a desiccator and weighed. The percentage of total ash was calculated with reference to air-dried drug.

Acid Insoluble ash

The ash was boiled with 25 ml of 2 M hydrochloric acid for 5 minutes, the insoluble matter was collected on an ash less filter paper, washed with hot water, ignited, cooled in a desiccator, and weighed. The percentage of acid insoluble ash was calculated with reference to the air-dried drug.

Water Soluble ash

The ash was boiled with 25 ml of water for 5 minutes, the insoluble matter on ash less filter paper collected, washed with hot water, ignited, cooled in a desiccator, and weighed. The weight of the insoluble matter from the weight of the total ash was subtracted; the difference represents the water soluble ash. The percentage of water insoluble ash was calculated with reference to the air-dried drug.

Loss on drying:

3gm of the drug is heated in a hot oven at 105^0 c to constant weight. The % of weight was calculated.

Potential of hydrogen *(pH)*:

The pH scale is logarithmic and runs from 0.0 to 14.0 with 7.0 being neutral. Readings less than 7.0 indicate acidic solutions, while higher readings indicate alkaline or base solutions.

Above mentioned Quantitative analysis results are showed in the Table 4.2.2.1

Thin layer chromatography:

Solvent system:

Toluene: Ethyl acetate (4:1.5).

TLC plate:

Aluminium plate precoated with silica gel $60F_{254}$ of 0.2 mm thickness (Merck).

Developing chamber:

Camag's twin trough chamber.

Visualizing reagent:

Vanillin-sulphuric acid reagent.

Extract Preparation:

4 g of the chooranam was soaked overnight in chloroform. Boiled on a water bath for 10 mins, filtered and concentrated to 10 ml.

Procedure:

The extract was applied on the TLC using capillary and developed in the solvent system. The developed TLC plate was air dried and photograph was taken in white light. Then dipped in vanillin-sulphuric acid reagent, heated in an oven at 105°C until the development of coloured spots and photograph taken.

4.2.2.3. SCANNING ELECTRON MICROSCOPE (SEM):

The Scanning Electron Microscope (SEM) is a microscope that was electrons rather than light to form an image. There are many advantages in using the SEM instead of a light microscope.

Resolution : 1.2 nm gold particle separation on a carbon substrate

Magnification: From a min of 12 X to greater than 1, 00,000 X

The SEM has a large depth of field, which allows a large amount of the sample to be in focus at one time. The SEM also produces images of high resolution, which means that closely spaced features can be examined at a high magnification. Preparation of the samples is relatively easy since most SEM one require the sample to be conductive.

The combination of higher magnification, larger depth of focus, greater resolution, and easy of sample observation marks the SEM one of the most heavily used instruments in research areas today.

4.2.2.4. FOURIER TRANSFORM INFRARED SPECTROSCOPY (FTIR)

Instrument Details**:**

Model : Spectrum one: FT-IR Spectrometer

Scan Range : MIR 450-4000 cm-1

Resolution : 1.0 cm-1

Sample required : 50 mg, solid or liquid.

Fourier Transform Infrared Spectroscopy (FTIR) is an analytical technique used to identify mainly organic materials. FTIR analysis results in absorption spectra which provide information about the chemical bonds and molecular structure of a material. The FTIR spectrum is equivalent to the "fingerprint" of the material and can be compared with cataloged FTIR spectra to identify the material.

Fourier transform infrared spectroscopy analytical capabilities:

- Identifies chemical bond, functional groups by the absorption of infrared radiation which excites vibrational modes in the bond
- Especially FTIR is capable of identifying the chemical bonds of organic materials
- Detects and Identifies organic contaminants
- Identifies water, phosphates, sulphates, nitrates, nitrites, and ammonium ions
- Detection limits vary greatly, but are sometimes $<10^{13}$ bonds/cm^3 or sometimes sub monolayer
- Useful with solids, liquids, or gases

To confirm the acid and basic radicals of the trial drug inorder to ensure the inorganic constituents

4.2.3. QUALITATIVE PHYTOCHEMICAL ANALYSIS:

Materials and methods:

- The roots of *Smilax zeylanica* were washed and shade dried.
- The roots were then milled to obtain the fine powder using an electric blender.
- The yield of extract was calculated.
- Phytochemical screening procedures were carried out to determine the biologically active compounds that contribute to the flavour, colour and other characteristics of roots.

Table. 4.2.3. Qualitative phytochemical analysis:

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
I.	**Test for Tannins:** Substance is shaken with water and added with lead acetate solution	Forms a white precipitate	Presence of tannins
II.	**Test for Saponin:** To a few mg of extract distilled water is added and shaken well. .	The formation of foam occurs	Presence of saponin
III.	**Test for Flavonoids:** Substance is dissolved in alcohol, added with magnesium bits and concentrated hydrochloric acid, and heated over a water bath.	The appearance of majenta colour	Presence of flavonoids
IV.	**Test for steroids:** The sample 2ml is mixed with 2 ml H_2SO_4 and 0.5 gm Acetic anhydride.	The solution turns in to blue to green colour	Presence of Steroids
V.	**Test for Cardiac glycoside (Keller-Killani Test)** Add 2 ml of glacial acetic acid containing a drop of ferric chloride solution and 0.5 ml of concentrated sulphuric acid to the chloroform extract of the plant.	Absence of the blue color in the acetic acetic acid layer	Absence of cardiac glycosides
VI.	**Test for Triterpenes:(Noller's Test)** To few mg of extract, add tin and thionyl chloride and heat in water bath.	Presence of purple colour	Presence of Triterpenes

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
VII..	**Test for Alkaloids (Dragendorff's Test)** Few mg of extract in separate test tube was warmed with 2% Sulphuric acid for 2 minutes. And it was filtered in separate test tube and few drops of Dragendorff's reagent were added.	The presence of orange red precipitate	Presence of alkaloids
VIII.	**Test for Phenolic compounds:** Substance in water is added with 5 % alcoholic ferric chloride.	The presence of dark blue or green colour	Presence of phenolic compounds
IX.	**Test for Coumarins:** To 1 ml of extract, 1ml of 10% NaOH was added.	Absence of Formation of yellow color	Absence of coumarins
X.	**Test for Anthraquinones** Few milligram of crude powder is shaken with 10 ml of benzene and filtered. To this filtrate, 0.5 ml of 10 % ammonia solution is added and the mixture is shaken well.	Absence of of the violet colour in the layer	Absence of anthraquinones

Herbal based plant products can be exploited with sustainable comparative and competitive advantage. Higher plant, being sources of medicinal compounds continue to play dominant role in maintaining human health since antiquities. Over 50% of all modern clinical drugs are of natural plant origin. (Stuffness and Douros, 1982).

4.2.4. PROXIMATE CHEMICAL ANALYSIS

Methodology for Chemcial Analysis

Preparation of Extract*:*

- Add 5 gm of the *Karuvilanchi ver chooranam* to 50ml of distilled water.
- Boil the solution for 20 minutes, cool and then filter.
- The extract is used for the following tests.

Table 4.2.4 Methodology for chemcial analysis

S.No	Experiment	Observation	Inference
1.	**Test for reducing Sugar :** To 5ml of Benedicts qualitative reagent, add 10 drops of extract, then boil for two minutes	Absence of Green / Yellow / Red Precipitate	Absence of Reducing Sugar
2.	**Test for Starch :** To 5 ml of extract add 2ml of acetic acid and then add few drops of N/50 Iodine Solution.	Presence of Blue Colour	Presence of Starch
3.	**Test for Proteins :** To 2 ml of extract, add 2ml of 5% Sodium Hydroxide mix and add 2 drops of Copper Sulphate Solution.	Presence of Violet or Purple Colour	Presence of Proteins
4.	**Test for amino Acid :** Place 2 drops of extract on a filter paper and allow to dry well. Then spray 1% ninhydrin over the same and allowed to dry.	Absence of Violet Colour	Absence of Amino Acid

S.No	Experiment	Observation	Inference
5.	**Test for Albumin :** To 2 ml of extract, add 2ml of Esboch's reagent.	Absence of Yellow Precipitate	Absence of Albumin
6.	**Test for Phosphate :** To 2ml of extract, add 2ml of ammonium Molybdate solution and 2ml of concentrated Nitric Acid.	Absence of Yellow Precipitate	Absence of Phosphate
7.	**Test for Sulphate :** To 2 ml of extract add 2ml of 4% ammonium oxalate solution.	Absence of White Precipitate	Absence of Sulphate
8.	**Test for Chloride :** Add 2ml of extract to dilute nitric acid till the effervescence ceases. Then add 2 ml of Silver Nitrate Solution.	Absence of Cloudy White Precipitate	Absence of Chloride
9.	**Test for Iron :** To 2ml of extract, add 2ml of ammonium thio cynate solution and add 2ml of concentrated Nitric Acid.	Presence of Red Colour	Presence of Iron
10.	**Test for Calcium :** To 2 ml of extract, add 2 ml of 4% ammonium Oxalate Solution.	Absence of White Precipitate	Absence of Calcium
11.	**Test for Sodium :** Make a paste with 2 pinches of the sample with Hcl and Introduce it into the blue flame.	Absence of Yellow Flame	Absence of Sodium
12.	**Test for Potassium :** Add a pinch of the sample to 2 ml of Sodium Nitrate Solution. Then add 2ml of Cobal Nitrate in 20% acetic acid.	Absence of Yellow Precipitate	Absence of Potassium

S.No	Experiment	Observation	Inference
13.	**Test for Zinc :** To 2ml of extract, add few drops of Sodium Hydroxide.	Absence of White Precipitate	Absence of Zinc
14.	**Test for Magnesium :** To 2ml of extract, add few drops of Sodium Hydroxide Solution	Absence of White Precipitate	Absence of Magnesium
15.	**Test for Alkaloids :** a. To 2ml of extract, add 2ml of Potassium Iodide Solution b. To 2ml of extract add 2ml of Picric Acid. c. To 2 ml of extract add 2ml of Phosphotunqstic Acid.	Presence of Red Colour Presence of Yellow Colour Presence of White Precipitate	Presence of Alkaloids Presence of Alkaloids Presence of Alkaloids
16.	**Test for Tannic Acid :** To 2ml of extract add 2 ml of Ferric Chloride Solution	Presence of Black Precipitate	Presence of Tannic Acid

4.3. TOXICITY STUDY

Materials and methods:

Animals

Albino mice (22–28 g) and Wistar rats (180–200 g) either sex were obtained from the animal house of animal housing facility of department of pharmacology, Vels University, Chennai. Animals were maintained at standard laboratory conditions and fed with standard feeding pellets (Sai durga foods, Bangalore). Prior to treatment, the animals were fasted for 10 and 12 h respectively. However, water was made available ad libitum. (Approval number: XIII/VELS/PCOL/16/2000/CPCSEA/IAEC/08.08.2012).

Experimental Methods

Acute toxicity

Acute oral toxicity test for the Karuvilanchi ver chooranam was carried out as per OECD Guidelines 425. As with other sequential test designs, care was taken to ensure that animals are available in the appropriate size and age range for the entire study. The test substance is administered in a single dose by gavage using a stomach tube or a suitable intubation cannula. The fasted body weight of each animal is determined and the dose is calculated according to the body weight. After the substance has been administered, food was withheld for a further 2 hours in mice. The animals were observed continuously for the first 4 h and then each hour for the next 24 h and at 6 hourly intervals for the following 48 h after administering of the test drug, to observe any death or changes in general behaviour and other physiological activities. Single animals are dosed in sequence usually at 48 h intervals.

However, the time interval between dosing is determined by the onset, duration, and severity of toxic signs. Treatment of an animal at the next dose was delayed until one is confident of survival of the previously dosed animal. General behavior, respiratory pattern, cardiovascular signs, motor activities, reflexes, change in skin and fur, mortality and the body weight changes were monitored daily. The time of onset, intensity, and duration of these signs, if any, was recorded.

4.4. PHARMACOLOGICAL STUDY:

Drugs and chemicals

Formalin, acetic acid, and CMC, all from Sigma-Aldrich Chemicals were the chemicals used. The standard drugs aspirin and Pentazocine was procured from the local market. All the other chemicals and drugs used were of analytical grade.

Evaluation of analgesic activity by Eddy's Hotplate method

The hot-plate test method was employed to assess the analgesic activity. The temperature of the cylinder was set at 55±0.5^{0}C. The experimental mice were divided into four groups. Each mouse acted as its own control. Prior to treatment, the reaction time of each mouse (licking of the forepaws or jumping response) was done at 0 and 10min interval. The average of the two readings was obtained as the initial reaction time. The reaction time following the administration of the *Karuvilanchi ver chooranam* (250, 500 mg/kg, p.o.), Pentazocine (5mg/kg) and Saline (p.o.), was measured at 30, 60and 120 minutes after a latency period of 30 mins. The Percentage analgesic activity was calculated.

Antinociceptive testing

The antinociceptive property of *Karuvilanchi ver chooranam* was tested using the model of writhing response in mice. Swiss albino mice of either sexes weighing 20-30 g were used. The writhing syndrome was elicited by an intraperitoneal injection of 0.7% acetic acid at the dose of 0.1ml/10 g body weight. Test substances and control vehicle were orally administered into the mice 30 min before acetic acid and the number of writhes was noted for 25 min beginning 5 min after acetic acid injection.

Evaluation of acute anti-inflammatory activity by plethysmometer method

Karuvilanchi ver chooranam Suspended with 2% carboxy methyl cellulose was prepared and the stock solution concentration was 200mg/ml. The animals were divided into four groups. Acute inflammation was produced by subplantar injection of 0.1 ml of 1% suspension of formalin in normal saline in the right hind paw of the rats. Paw volume was measured plethysmometrically at '0' –'2' hours after formalin injection. The animals were treated with *Karuvilanchi ver chooranam* (250, 500 mg/kg., orally). Saline (3 ml/kg, orally) treated animals served as control and acetyl salicylic acid (100 mg/kg,

orally) was administered as standard drug. The drugs were administered simultaneously with formalin injection. Mean increase in paw volume was measured and Percent inhibition of test drugs was calculated in comparison with vehicle control (100%).

Statistical data

Data were presented as mean ± S.E.M. Statistical differences between control and treated groups were tested by one way ANOVA followed by dunnet's test.

4.5. CLINICAL ASSESSMENT:

Nowadays Life style has changed in many ways. Sedentary Lifestyle and lack of exercise are also responsible for osteoarthritis. I have selected *Karuvilanchi ver chooranam*, a herbal medicine for this clinical trial to prove its safety and efficacy against Osteoarhritis.

Objectives

The study was conducted on Osteoarhritis patients to assess the anti inflammatory and analgesic activity of ***"Karuvilanchi ver chooranam"*** clinically, both in-patients and out-patients of both sex and varying age groups.

Study Centre

The clinical study for **osteoarhritis** is carried out in outpatient department and in patient ward of Govt.Siddha medical college hospital and Arignar Anna Indian Hospital, Arumbakkam, Chennai-106.

Design of the study:

Open clinical trial, Phase II B

Selection:

50 patients from both sexes of various age groups were selected for clinical trial. Among 50 patients 40 patients were treated as out-patients, 10 patients were treated as in patients. The selection was based on the inclusion and exclusion criteria. They were clinically diagnosed on the basis of siddha principles with modern laboratory findings.

Registration Process

To register a patient, the following documents are required

- Copy of required laboratory tests
- Signed patient consent form

I verified the eligibility and assigned a patient study number, drug dose and registered the patient on the study.

Criteria selection:

Criteria for inclusion:

Patients with osteoarthritis are eligible for entry to the trial if the following criteria are satisfied.

The criteria of inclusion are:

- Morning stiffness
- Pain
- Swelling
- Restricted range of movements
- Radiological findings of OA
- Algo functional index above 7
- Co operative patients
- The previous drug regimen if any have been with held for 24 hours before the clinical trial.

Criteria for exclusion:

- Rheumatoid arthritis
- AIDS
- Malignancy
- Pregnant and lactating women
- TB
- Renal diseases
- Cardio vascular disorder
- Age below 10 years
- Syphilis

Withdrawal criteria:

Patients were removed from study when any of the criteria listed below applies. In the absence of treatment delays due to adverse events, treatment may continue for 2 cycles or until one of the following criteria applies:

- Disease progression,

- Deterioration of vital signs with cardiac, respiratory, hepatic, renal and CNS changes.
- Intercurrent illness that prevents further administration of treatment,
- Unacceptable adverse event(s),
- Patient decides to withdraw from the study, or
- General or specific changes in the patient's condition render the patient unacceptable for further treatment in the judgment of the investigator.

Routine examination and assessment:

- The full details of history and physical examination of the patients were recorded as per the proforma .The clinical assessment was done initially at the end of every week during treatment and at the end of the follow up. The laboratory investigation and the physiological parameters were recorded initially at the end of the treatment and at the end of follow up as per the proforma.

Dosage:

The trial drug ***Karuvilanchi ver chooranam*** was given in the dose of 1gram with hotwater depending upon the severity of the case.

Administration of the drug:

Form of the medicine	: *Chooranam*
Route of Administration	: Enteral
Dose	: 1g
Anubanam (Vehicle)	: Hot water
Times of Administration	: Two times a day; after food
Duration	: 7 weeks

Diet restriction and medical advice:

- The patients were instructed to take easily digestible foods.
- They were advised to take, healthy food. Avoid bitter gourd, agathi greens, brinjal, and non-vegetarian diet.
- The patient was advised to avoid cold damp climate.
- The patient was advised to take rest. But prolonged immobilization should be avoided.
- The clinical improvement was observed and recorded in the proforma of case sheet.

Trial conduct:

The study was conducted in compliance with the protocol approved by the Institutional Review Board, and according to Good Clinical Practice standards. No deviation from the protocol was implemented without the prior review and approval of the IRB.

Classification of results

1. **Good Response**
   a. Relief of Symptoms above 75%
   b. Laboratory parameter findings towards normalcy.
2. **Fair Response**
   a. 50% to 75% relief in symptoms.
   b. Significant improvement in laboratory parameter.
3. **Poor Response**
   25% to 49% relief in symptoms and minimal improvement in laboratory parameters.
4. **No Response**
   No relief in symptoms and no significant improvement in laboratory parameters.

Follow up:

Assessment was done every three days before treatment and after treatment. During this period clinical assessment and laboratory investigation was carried out.

Statistical analysis

The data will be tabulated and analyzed by students 'T' test.

Ethical review

The protocol and any amendments were submitted to Govt siddha medical college, Chennai – 106 (IEC) and got formal approval to conduct the study. The decision of the IEC concerning the conduct of the study was made in writing to the investigator. All subjects for this study was provided a consent form describing this study and provided sufficient information for subjects to make an informed decision about their participation in this study. This consent form was submitted with the protocol for review and approval by the IEC. The formal consent of a subject, using the IEC-approved consent form, was obtained before that subject was submitted to any study procedure. This consent form was signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

4.5.1.1 Clinical study of *Karuvilanchi ver chooranam* in osteoarthritis

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
1.	5852	KUMAR	45/M	11.6.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	1.11.2012	FAIR
2.	5807	VALLIAMMAL	55/F	11.6.2012	Pain & swelling in both knee joints, morning stiffness ⊕	4.9.2012	GOOD
3.	8053	RAMADAS	60/M	20.6.2012	Pain & swelling in both knee joints, morning stiffness ⊕	6.8.2012	GOOD
4.	851	MISBARA	57/F	28.6.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.11.2012	GOOD
5.	2698	MALLIGA	60/F	3.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	6.9. 2012	GOOD
6.	2764	MANIKKAM	60/M	5.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	18.9.2012	GOOD
7.	3228	REVATHI	45/F	7.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	1.11.2012	GOOD
8.	4000	JAYASHREE	35/F	10.7.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	5.9.2012	GOOD
9.	4443	VIJAYALAKSHMI	45/F	12.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	9.9.2012	GOOD
10.	6290	BANUMATHI	59/F	19.7.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	5.9.2012	FAIR

4.5.1.2. Clinical study of *Karuvilanchi ver chooranam* in osteoarthritis

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
11.	7545	ANANDAN	53/M	24.7.2012	Pain & swelling in left knee joint, morning stiffness ⊕	22.11.2012	GOOD
12.	7590	MOHAMMED EHIYA	61/M	24.7.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	7.12.2012	FAIR
13.	7656	SUBRAMANIUM	68/M	24.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.10.2012	GOOD
14.	8738	SHANTHI	48/F	28.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	8.11.2012	GOOD
15.	8830	SRINIVASAN	45/M	29.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	4.9.2012	GOOD
16.	8856	SAGHADEV1	43/F	29.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	18.9.2012	GOOD
17.	9197	RAGOTHAMAN	62/M	30.7.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	2.9.2012	GOOD
18.	125	SHANTHI	48/F	2.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	15.9.2012	FAIR
19.	515	VIJAYALAKSHMI	45/F	4.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	19.9.2012	GOOD
20.	528	KANCHANA	60/F	4.8.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	20.11.2012	GOOD

4.5.1.3. Clinical study of *Karuvilanchi ver chooranam* in osteoarthritis

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
21.	2756	YOGESHWARI	41/F	14.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	8.11.2012	FAIR
22.	2974	ARPUTHAM	35/F	15.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	23.10.2012	GOOD
23.	3529	KANNIGA	42/F	17.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.10.2012	FAIR
24.	4309	MUSTHAPHA	54/M	21.8.2012	Pain & swelling in left knee joint, morning stiffness ⊕	19.10.2012	GOOD
25.	5895	THILAGAM	50/F	28.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	12.10.2012	FAIR
26.	5949	VALLIAMMA	65/F	28.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	8.11.2012	GOOD
27.	7379	ANJALAI	55/F	4.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	12.10.2012	GOOD
28.	7410	PUSHPA	46/F	4.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.11.2012	GOOD
29.	7650	VENUGOPAL	50/M	5.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	8.11.2012	GOOD
30.	8743	SELVAN	61/M	10.9.2012	Pain & swelling in both knee joints , morning stiffness ⊕	10.10.2012	GOOD

4.5.1.4. Clinical study of *Karuvilanchi ver chooranam* in osteoarthritis

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
31.	9093	RAMALINGAM	60/M	11.9.2012	Pain & swelling in right knee joint, morning stiffness ⊕	28.10.2012	GOOD
32.	9945	KANAGA	45/F	14.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	24.10.2012	FAIR
33.	9965	GOWRI	58/F	14.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	8.11.2012	GOOD
34.	1457	VARADHAN	47/M	2.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	24.12.2012	GOOD
35.	2645	RANGASAMY	65/M	26.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.11.2012	GOOD
36.	3808	NAGHARANI	45/F	1.10.2012	Pain & swelling in both knee joints, morning stiffness ⊕	18.11.2012	GOOD
37.	5646	NIRMALA	42/F	8.10.2012	Pain & swelling in both knee joints, morning stiffness ⊕	12.11.2012	GOOD
38.	8037	KASTHURI	57/F	18.10.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.12.2012	GOOD
39.	3081	BIROSE	35/F	17.11.2012	Pain & swelling in both knee joints, morning stiffness ⊕	9.12.2012	GOOD
40.	3683	YASINBEEVI	60/F	17.11.2012	Pain & swelling in both knee joints, morning stiffness ⊕	30.12.2012	GOOD

4.5.1.5. Clinical study of *Karuvilanchi ver chooranam* in osteoarthritis

Sl.No.	I.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
1.	711	SIKANDAR BANU	52/F	18.6.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	1.7.2012	FAIR
2.	1055	MANI	55/M	18.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	1.8.2012	GOOD
3.	1090	JEYAMARY	55/F	23.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	16.8.2012	GOOD
4.	851	RANI RAMADAS	57/F	25.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	3.8.2012	GOOD
5.	1136	KANNAN	62/M	28.7.2012	Pain & swelling in both knee joints, morning stiffness ⊕	17.9. 2012	FAIR
6.	1232	TAMILSELVI	50/F	8.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	5.9.2012	GOOD
7.	1338	MARY	43/F	24.8.2012	Pain & swelling in both knee joints, morning stiffness ⊕	8.9.2012	GOOD
8.	1355	MARAGATHAM	55/F	26.8.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	29.9.2012	GOOD
9.	78	VASUDEVAN	62/M	24.9.2012	Pain & swelling in both knee joints, morning stiffness ⊕	12.10.2012	GOOD
10.	156	RAMAJEYAM	59/M	10.10.2012	Pain ⊕ in both knee joints, morning stiffness ⊕	22.10.2012	FAIR

4.5.2.1. Haematological parameters of patients of osteoarthritis

Sl. No.	O.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr								
1.	5852	KUMAR	45/M	8570	66	31	3	9500	50	46	4	-	70	20	45	9.8	10.6	NIL	NIL	NIL	NIL	NIL	NIL
2.	5807	VALLIAMMAL	55/F	9400	58	37	5	7800	62	34	4	40	88	10	20	10.4	13.7	+++	NIL	4-5PC 1-2EC	NIL	NIL	OPC
3.	8053	RAMADAS	60/M	10100	62	28	10	8700	61	34	5	4	10	4	10	12	13.8	NIL	NIL	OPC	NIL	NIL	NIL
4.	851	MISBARA	57/F	10600	64	32	4	8800	59	37	4	20	50	8	15	11.6	12.2	NIL	NIL	10-12EC	NIL	NIL	NIL
5.	2698	MALLIGA	60/F	9700	58	35	7	9200	58	38	4	29	75	14	35	9.0	11.5	NIL	NIL	OEC	NIL	NIL	NIL
6.	2764	MANIKKAM	60/M	9700	60	34	6	9800	60	36	4	7	13	6	10	12.0	13.1	NIL	NIL	OPC	NIL	NIL	OPC
7.	3228	REVATHI	45/F	9200	58	36	6	8100	61	34	5	11	20	6	12	10.8	11.5	NIL	NIL	OEC	NIL	NIL	NIL
8.	4000	JAYASHREE	35/F	8100	55	38	7	8800	58	34	8	20	50	8	20	8.0	10.2	NIL	NIL	NIL	NIL	NIL	NIL
9.	4443	VIJAYALAKSHMI	45/F	9600	58	39	5	9900	60	35	5	20	45	8	18	11	12.2	NIL	NIL	NIL	NIL	NIL	NIL
10.	6290	BANUMATHI	59/F	8800	56	30	5	9700	69	27	4	25	52	7	18	9.8	12.1	NIL	NIL	NIL	NIL	NIL	NIL

4.5.2.2. Haematological parameters of patients of osteoarthritis

Sl. No.	O.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr								
11.	7545	ANANDAN	53/M	9800	59	36	5	9700	60	36	4	17	52	7	20	13	14.8	NIL	NIL	NIL	NIL	NIL	NIL
12.	7590	MOHAMMED EHIYA	61/M	10100	64	31	5	7600	52	40	8	7	25	6	21	12.4	13.8	NIL	NIL	NIL	NIL	NIL	NIL
13.	7656	SUBRAMANIUM	68/M	9000	57	36	7	9500	59	36	5	20	44	8	22	11.6	12.2	NIL	NIL	OPC	NIL	NIL	NIL
14.	8738	SHANTHI	48/F	9700	60	34	6	9200	62	34	4	50	85	10	18	10.2	11.3	NIL	NIL	OEC	NIL	NIL	NIL
15.	8830	SRINIVASAN	45/M	8700	62	31	7	8000	56	37	7	26	50	7	18	9.6	10.3	NIL	NIL	NIL	NIL	NIL	NIL
16.	8856	SAGHADEV1	43/F	9600	65	29	6	9200	64	32	4	26	42	8	17	10.6	11.4	NIL	NIL	NIL	NIL	NIL	NIL
17.	9197	RAGOTHAMAN	62/M	9200	62	35	3	9800	63	35	2	35	54	8	22	9.6	10.1	NIL	NIL	NIL	NIL	NIL	NIL
18.	125	SHANTHI	48/F	8,200	67	30	3	8500	56	38	5	26	58	7	20	10.8	13.2	NIL	NIL	NIL	NIL	NIL	NIL
19.	515	VIJAYALAKSHMI	45/F	9,600	64	32	4	9800	63	32	5	24	52	8	16	10.4	12.6	NIL	NIL	NIL	NIL	NIL	NIL
20.	528	KANCHANA	60/F	9000	56	39	5	9300	62	35	3	5	20	5	13	10	12.4	NIL	NIL	NIL	NIL	NIL	NIL

4.5.2.3. Haematological parameters of patients of osteoarthritis

Sl. No.	O.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr								
21.	2756	YOGESHWARI	41/F	9600	66	31	3	8500	52	44	4	24	70	20	45	9.8	12.1	NIL	NIL	NIL	NIL	NIL	Opc
22.	2974	ARPUTHAM	35/F	7000	65	31	4	7800	62	33	5	18	41	10	20	10.9	13.7	NIL	NIL	NIL	NIL	NIL	NIL
23.	3529	KANNIGA	42/F	8200	75	20	5	6300	51	44	5	25	70	18	40	9.7	10.2	NIL	NIL	NIL	NIL	NIL	NIL
24.	4309	MUSTHAPHA	54/M	9700	54	41	5	7800	59	35	2	12	34	7	18	9.8	11.2	NIL	NIL	OPC	NIL	NIL	NIL
25.	5895	THILAGAM	50/F	9400	55	39	6	9600	58	38	4	20	43	12	35	10.8	11.5	NIL	NIL	OEC	NIL	NIL	NIL
26.	5949	VALLIAMMA	65/F	10,200	60	32	8	9800	62	34	4	22	54	9	22	10.0	12.2	NIL	NIL	OPC	NIL	NIL	Opc
27.	7379	ANJALAI	55/F	8400	52	43	5	9100	61	36	3	24	40	7	12	9.0	11.6	NIL	NIL	OPC	NIL	NIL	NIL
28.	7410	PUSHPA	46/F	9600	59	35	6	8600	58	36	6	20	46	12	20	10.8	12.2	NIL	NIL	NIL	NIL	NIL	NIL
29.	7650	VENUGOPAL	50/M	10,200	64	32	4	9900	62	33	5	14	30	8	18	13.8	15.2	NIL	NIL	NIL	NIL	NIL	NIL
30.	8743	SELVAN	61/M	9300	59	37	4	9700	65	31	4	4	12	4	8	15	16.4	NIL	NIL	NIL	NIL	NIL	NIL

4.5.2.4. Haematological parameters of patients of osteoarthritis

Sl. No.	O.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr								
31.	9093	RAMALINGAM	60/M	8800	58	36	6	8400	60	36	4	16	50	7	21	12	14.8	NIL	NIL	OPC	NIL	NIL	NIL
32.	9945	KANAGA	45/F	9000	55	39	6	8800	61	33	6	26	50	8	23	8	13.4	NIL	NIL	OEC	NIL	NIL	NIL
33.	9965	GOWRI	58/F	9600	59	35	6	9400	59	36	5	30	60	8	18	12.2	14.2	NIL	NIL	NIL	NIL	NIL	NIL
34.	1457	VARADHAN	47/M	9800	59	36	5	9300	60	36	4	16	40	8	18	12.2	14.6	NIL	NIL	OPC	NIL	NIL	NIL
35.	2645	RANGASAMY	65/M	9700	59	38	3	9200	56	36	8	14	30	7	19	12	13.6	NIL	NIL	NIL	NIL	NIL	NIL
36.	3808	NAGHARANI	45/F	9600	65	30	5	9700	65	31	4	25	48	7	18	10.2	11.4	NIL	NIL	NIL	NIL	NIL	NIL
37.	5646	NIRMALA	42/F	8200	60	35	5	9800	60	34	6	30	52	10	22	9.4	10.6	NIL	NIL	OEC	NIL	NIL	NIL
38.	8037	KASTHURI	57/F	10,700	60	36	4	8700	58	38	4	25	70	8	20	10.8	11.6	NIL	NIL	OEC	NIL	NIL	NIL
39.	3081	FIROZA	35/F	10,000	58	38	4	9800	65	30	5	18	32	7	18	10	11.6	NIL	NIL	NIL	NIL	NIL	NIL
40.	3683	YASINBEEVI	60/F	10,200	63	32	5	9600	62	35	3	30	62	5	18	11.4	12.6	NIL	NIL	NIL	NIL	NIL	NIL

4.5.2.5. Haematological parameters of patients of osteoarthritis

Sl. No.	I.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				Hb(Gm)		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT		AT		BT	AT						
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1hr			Alb	Sug	Dep	Alb	Sug	Dep
1.	711	SIKANDAR BANU	52/F	9600	65	31	4	8600	54	44	2	25	50	14	36	9.8	10.4	NIL	NIL	NIL	NIL	NIL	Opc
2.	1055	MANI	55/M	7200	64	32	4	7800	60	37	3	12	40	12	20	10.8	11.8	NIL	NIL	NIL	NIL	NIL	NIL
3.	1090	JEYAMARY	55/F	9200	75	20	5	8300	53	44	3	25	70	18	36	9.8	10.4	NIL	NIL	NIL	NIL	NIL	NIL
4.	851	RANI RAMADAS	57/F	7400	68	26	6	7800	61	35	4	12	30	7	14	9.4	10.8	NIL	NIL	NIL	NIL	NIL	NIL
5.	1136	KANNAN	62/M	9700	54	31	7	9200	60	36	4	29	75	14	35	9.0	11.6	NIL	NIL	OEC	NIL	NIL	NIL
6.	1232	TAMILSELVI	50/F	10,000	61	34	5	9800	60	36	4	24	6	9	22	12.0	12.8	NIL	NIL	OPC	NIL	NIL	Opc
7.	1338	MARY	43/F	8300	66	30	4	8600	61	36	3	14	28	5	12	11.0	11.8	NIL	NIL	OPC	NIL	NIL	NIL
8.	1355	MARAGATHAM	55/F	8100	55	38	7	8600	58	36	6	20	42	9	22	9.6	10.8	NIL	NIL	NIL	NIL	NIL	NIL
9.	78	VASUDEVAN	62/M	9800	57	39	4	9900	62	33	5	18	46	8	18	12	12.6	NIL	NIL	NIL	NIL	NIL	NIL
10.	156	RAMAJEYAM	59/M	9600	66	30	4	9500	65	31	4	25	52	14	35	9.8	10.8	NIL	NIL	NIL	NIL	NIL	NIL

4.5.3 Algofunctional index before and after treatment with *Karuvilanchi ver chooranam*

Sl.No	OP/IP.No	Name	Age/ Sex	Algo functional index	
				Before treatment	After Treatment
1.	5852	Kumar	45/M	8	5
2.	5807	Valliammal	55/F	9	4
3.	8053	Ramadas	60/M	10	3
4.	851	Misbara	57/F	9	3
5.	2698	Malliga	60/F	10	2
6.	2764	Manikkam	60/M	8	4
7.	3228	Revathi	45/F	9	3
8.	4000	Jayashree	35/F	8	2
9.	4443	Vijayalakshmi	45/F	9	4
10.	6290	Banumathi	59/F	9	2
11.	7545	Anandan	53/M	8	5
12.	7590	Mohammed ehiya	61/M	9	3
13.	7656	Subramanium	68/M	8	2
14.	8738	Shanthi	48/F	8	5
15.	8830	Srinivasan	45/M	11	3
16.	8856	Saghadev1	43/F	8	4
17.	9197	Ragothaman	62/M	9	2
18.	125	Shanthi	48/F	10	5
19.	515	Vijayalakshmi	45/F	8	6
20.	528	Kanchana	60/F	12	3
21.	2756	Yogeshwari	41/F	10	4
22.	2974	Arputham	35/F	9	5
23.	3529	Kanniga	42/F	8	6
24.	4309	Musthapha	54/M	8	5
25.	5895	Thilagam	50/F	9	4

4.5.4 Algofunctional index before and after treatment with *Karuvilanchi ver chooranam*

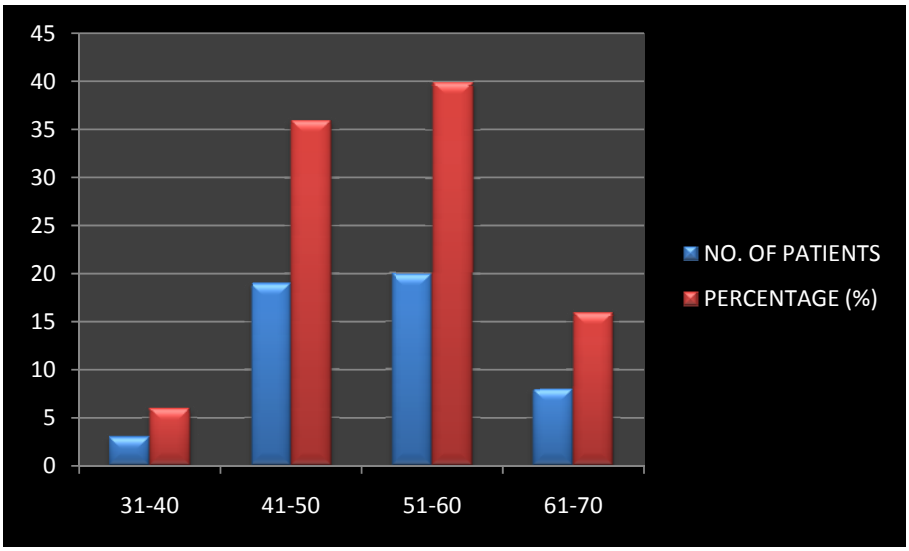
Sl.no	OP/IP.No	Name	Age/ Sex	Algo functional index	
				Before treatment	After Treatment
26.	5949	Valliamma	65/F	8	3
27.	7379	Anjalai	55/F	9	2
28.	7410	Pushpa	46/F	8	3
29.	7650	Venugopal	50/M	8	4
30	8743	Selvan	61/M	11	5
31.	9093	Ramalingam	60/M	11	3
32	9945	Kanaga	45/F	9	2
33.	9965	Gowri	58/F	8	6
34.	1457	Varadhan	47/M	8	2
35.	2645	Rangasamy	65/M	10	3
36.	3808	Nagharani	45/F	8	4
37.	5646	Nirmala	42/F	8	2
38.	8037	Kasthuri	57/F	12	5
39.	3081	Firoza	35/F	11	4
40.	3683	Yasinbeevi	60/F	11	3
41.	711	Sikandar banu	52/F	10	2
42.	1055	Mani	55/M	9	4
43.	1090	Jeyamary	55/F	9	2
44.	851	Rani ramadas	57/F	9	5
45.	1136	Kannan	62/M	8	2
46.	1232	Tamilselvi	50/F	11	4
47.	1338	Mary	43/F	9	3
48.	1355	maragatham	55/F	9	2
49.	78	Vasudevan	62/M	8	3
50.	156	Ramajeyam	59/M	11	2

CLINICAL ASSESSMENT

4.5.4. Age wise distribution

Sl. No	Age in years	No. Of patients	Percentage (%)
1	31-40	3	6
2	41-50	19	36
3	51-60	20	40
4	61-70	8	16
Total		50	100

4.5.4. Age wise distribution



Inference:

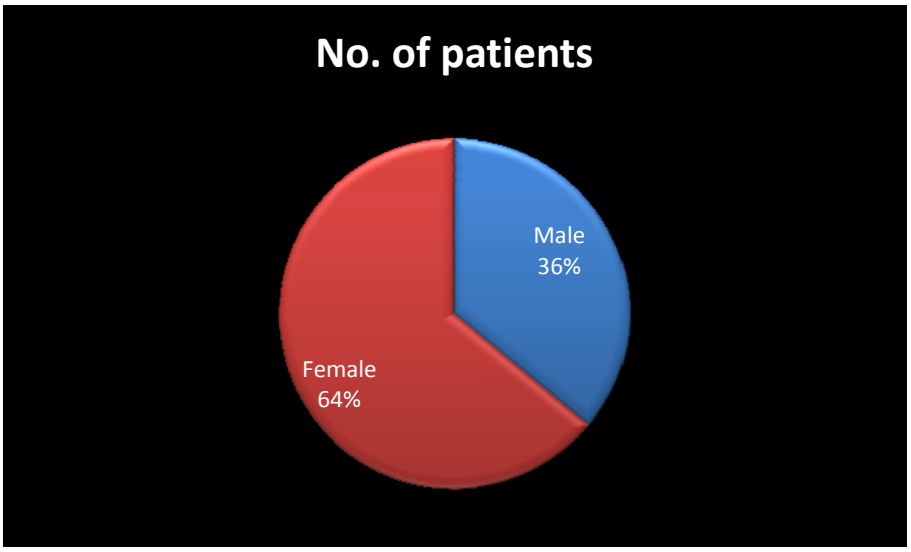
Among 50 patients,

- 3 patients belongs to the age group of 31-40 years
- 19 patients belongs to the age group of 41-50 years
- 20 patients belongs to the age group of 51-60 years
- 8 patients belongs to the age group of 61-70 years

4.5.5. Sex distribution

Sl. No	Sex	No. of patients	Percentage
1	Male	18	36
2	Female	32	64
Total		50	100

4.5.5. Sex distribution



Inference:

Among 50 patients,

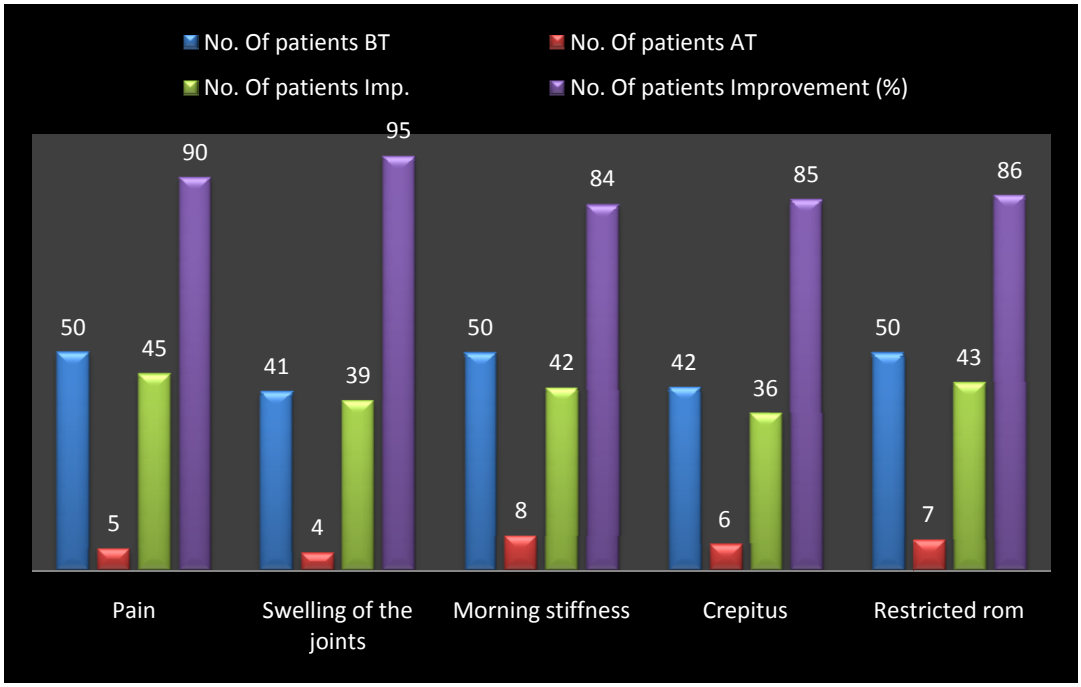
- 18 patients were male
- 32 patients were female

Results and discussion of clinical assesment

4.5.6 Improvement in signs and symptoms

Sl. No	Signs and symptoms	No. Of patients			
		BT	AT	Imp.	Improvement (%)
1	Pain	50	5	45	90
2	Swelling of the joints	41	4	39	95
3	Morning stiffness	50	8	42	84
4	Crepitus	42	6	36	85
5	Restricted ROM	50	7	43	86

4.5.6 Improvement in signs and symptoms



Discussion:

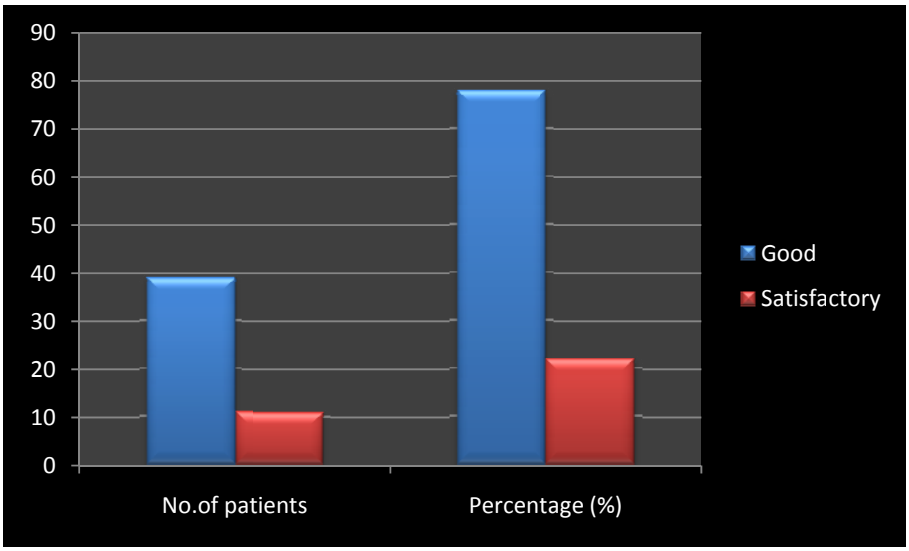
Among 50 patients,

- 45 out of 50 patients were relieved from pain
- 39 out of 41 patients were relieved from swelling
- 42 out of 50 patients were relieved from morning stiffness
- 36 out of 42 patients showed improvement as the crepitus reduced.
- 43 out of 50 patients were relieved from restricted ROM

4.5.7 Gradation report

Sl. No	Level of improvement	No.of patients	Percentage (%)
1	Good	39	78
2	Satisfactory	11	22
TOTAL		50	100

4.5.7 Gradation report



Clinical study:

50 patients of both sexes were selected. Among the 50 patients, 40 patients were treated as out- patients in the Post graduate department of Gunapadam, Govt.Siddha medical college hospital and Govt. Arignar Anna hospital, Arumbakkam, Chennai- 106. 10 patients were treated as in - patients.

The patients were observed regularly. The trial drug *Karuvilanchi ver chooranam* was given in the dose of 1gram with hotwater twice a day after meals. On administration of *Karuvilanchi ver chooranam* 1gram with hotwater twice a day for 7 weeks showed significant anti inflammatory and analgesic activity. Hot water which was used as vehicle also has anti-oxidant property as per classical siddha literature.

Among 50 patients, 45 out of 50 patients were relieved from Pain. 39 out of 41 patients were relieved from swelling of the joints. 42 out of 50 patients were relieved from morning stiffness. 36 out of 42 patients showed improvement in crepitus. 43 out of 50 patients were relieved from restricted ROM.

The results revealed that the drug possess 78% good relief, 22% fair results.

4.5.8. Statistical analysis

Descriptive statistical analysis of algofunctional index in patients BT & AT

Table. 4.5.8. A

"**p" value & statistical significance:**

Treatment	Mean	S.D	S.E.M
Before treatment	9.14	1.20	0.17
After treatment	3.48	1.25	0.18

Table.A4.5.8 Showing Paired "t" test result.

From the table we calculated the descriptive statistic like Mean, S.D & S.E.M of Mean for the improvement score before and after treatment.

"t" Table. 4.5.8 B

t-Table	S.D	"t" Value	"p" Value
Pre vs Post	0.255	22.2024	<0.0001

The two-tailed P value is less than 0.0001

By conventional criteria, this difference is considered to be extremely statistically significant.

5. RESULTS AND DISCUSSION

The word drug itself comes from the Swedish word “drug”, which means “dried plant”. Dried root powder of *Smilax zeylanica (Karuvilanchi verchooranam)* was taken for its anti inflammatory and analgesic activity.

Regarding the drug availability, this trial drug is available throughout the year for the treatment. Here, various studies have been carried out in this trial drug. The study includes literary collections, Pharmacognostic study, physico and Phytochemical analysis, toxicity study, pharmacological study, and clinical study. The drug has been selected for the treatment of *Osteoarthritis* in reference with *Vathanithanam 800.*

4.2.1. Pharmacognostic aspect of *Smilax zeylanica*

Anatomy of the root

Diagnostic features

Both thin and thick roots were studied. The thin root is 1.7mm in diameter (Fig 4.2.1.1.1). It consists of epidermis, exodermis, cortex, pith and several vascular strands. The epidermis is single layered; the cells are brachy – sclereids; the cells are squarish in shape with very thick walls and narrow cell – lumen; the cell walls have dense, canal – like simple pits (Fig 4.2.1.2.1). Epidermal cells are 30µm thick.

Inner to the epidermis is a single layer of darkly stained cell layer called exodermis. The cells of the exodermis are highly thick walled and lignified; the cell lumen is reduced to narrow area. (Fig .4.2.1.2.1).

Ground tissue is differentiated into outer wide zone of sclerenchyma cells or fibres. The fibres are thick walled and lignified. The cell lumen is wide (Fig4.2.1.2; 4.2.1.3.12). The central core is wide and forms the parenchymatous pith. (Fig.4.2.1.1.1). some of the pith cells are filled with dense tannin contents (fig 4.2.1.1.1, 4.2.1.2.1).

The vascular system consists of radial vascular strands which are arranged in regular circle, there are about 27 xylem strands alternating with equal number of phloem strands. The xylem and phloem strands are embedded in the outer zone of sclerenchyma tissue. The xylem and phloem have exarch protoxylem and protophloem respectively.

Thick root:

The thick root is 3.7mm in diameter. Its structure is basically similar to that of thin root, with minor differences. The outer epidermal cells of sclerotic layer is broken and reduced in thickness at several places in the thick root. (Fig.4.2.1.2.).The number of vascular strands is more in the thick root. The exodermal layer is thin. The xylem strands are in uniseriate radial rows and are larger than those of the thin root. The pith is disintegrated and the pith tissue is partly preserved. In the pith region there are wide circular canals or cavities ensheathed by one or two layers of thick walled cells. (Fig.4.2.1.1.).

Structure of the vascular strands

The xylem strands consist of one to three rows of angular, thin walled wide cells which are compactly grouped into spindle shaped segments (Fig4.2.1.2.1) In the thick root, the xylem segments consist of single radial row of tangentially elongate semi circular or rectangular cells (Fig4.2.1.2.2). The phloem strands are top shaped with exarch proto xylem point. They consist of wide, angular thin walled metaphloem cells; The cells become gradually narrow towards the protophloem end. (Fig.4.2.1.3.2)

Crystals:

In some of the pith cells are seen calcium oxalate crystals. The crystals are thin needles called raphides. Numerous needles are bundled together and occur in vertical position with in the cells. In transverse sections, the needles appear as closely aggregated circular bodies (Fig4.2.1. 3.3).

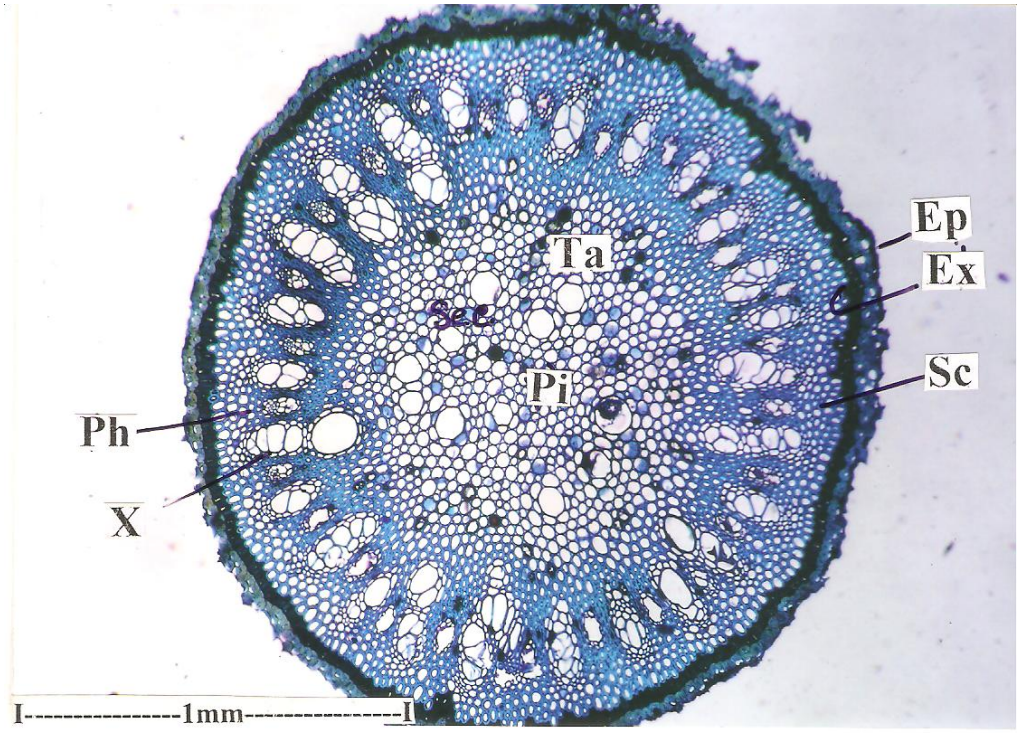


Fig.4.2.1.1.1 T.S of thin root –entire view

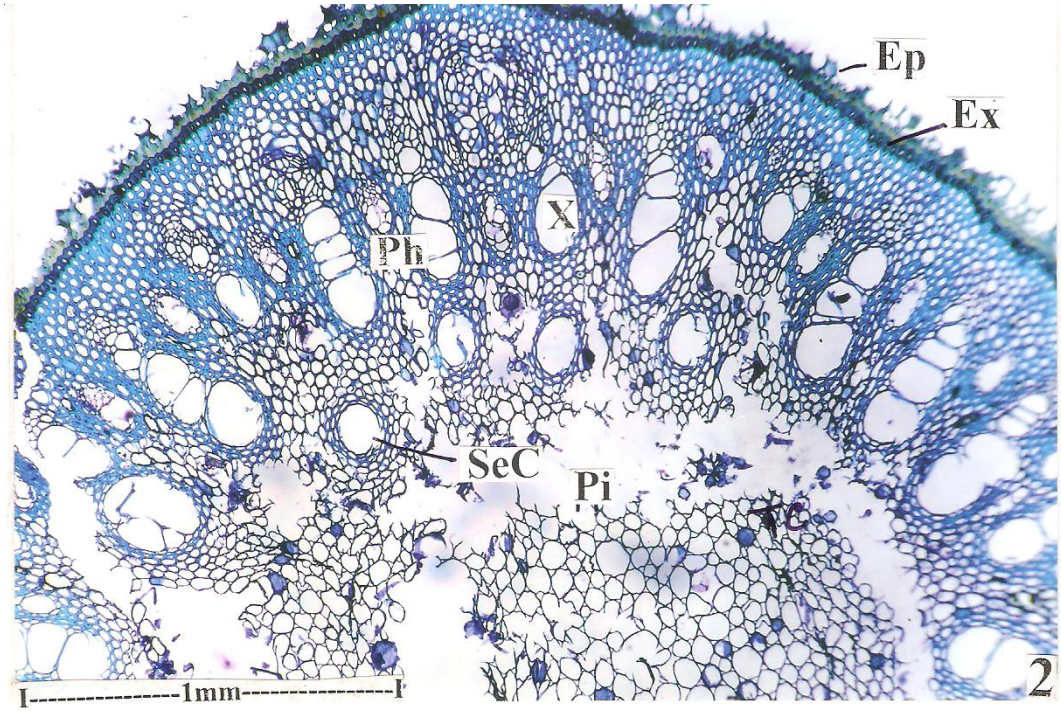


Fig.4.2.1.1.2 T.S of thick root – half sector

Ep - Epidermis	**Ph - Phloem**	**Ta - Tannin**
Ex – Exodermis	**Sc – Sclerenchyma**	**Tc – Tannin cell**
Pi - Pith	**Sec -Secretory cavity**	**X – Xylem**

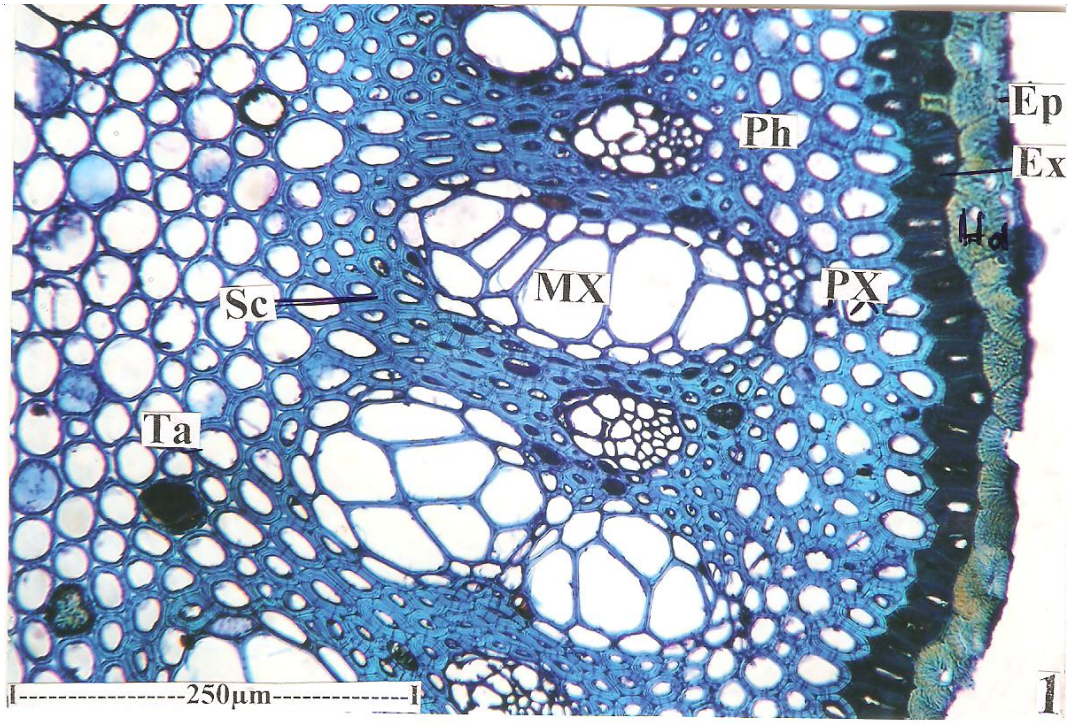


Fig.4.2.1.2.1 T.S. of thin root – A sector enlarged showing radial alignment of exarch xylem and phloem

Ep – Epidermis Sc – Sclerenchyma PX – Protoxylem Mx – Metaxylem

Ex – Exodermis Ph – Phloem Ta - Tannin

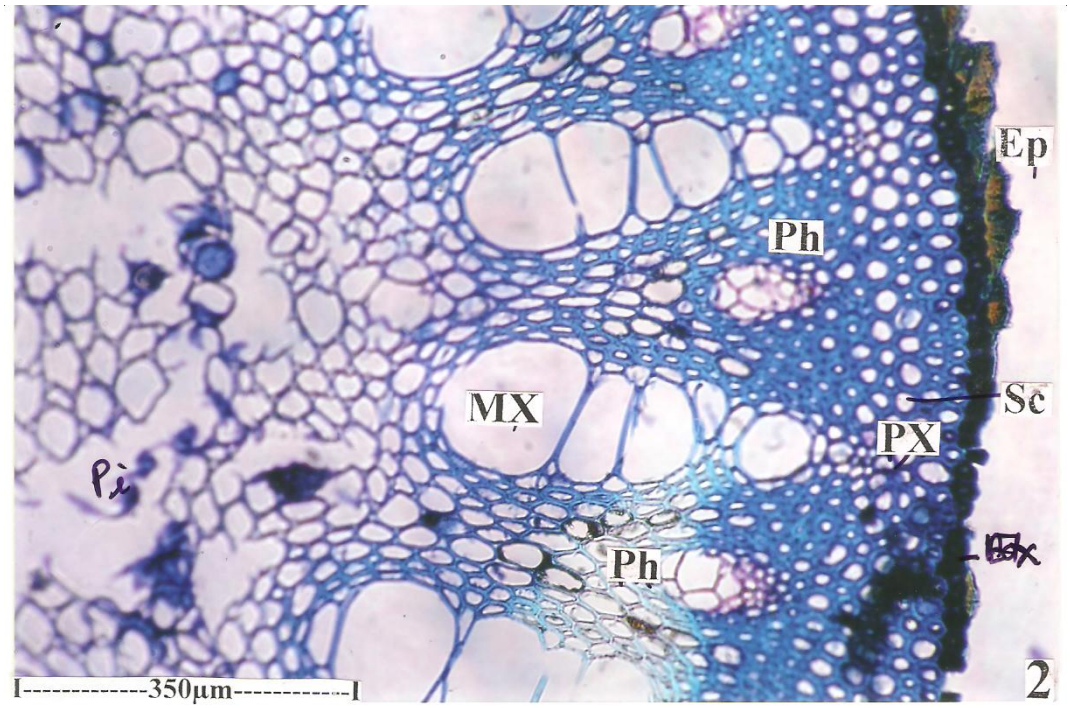


Fig.4.2.1.2.2 T.S of thick root - a sector showing exarch xylem and phloem strands

Mx – Metaxylem Ph – Phloem Ep – Epidermis Pi –Pith Sc – Sclerenchyma

PX - Protoxylem

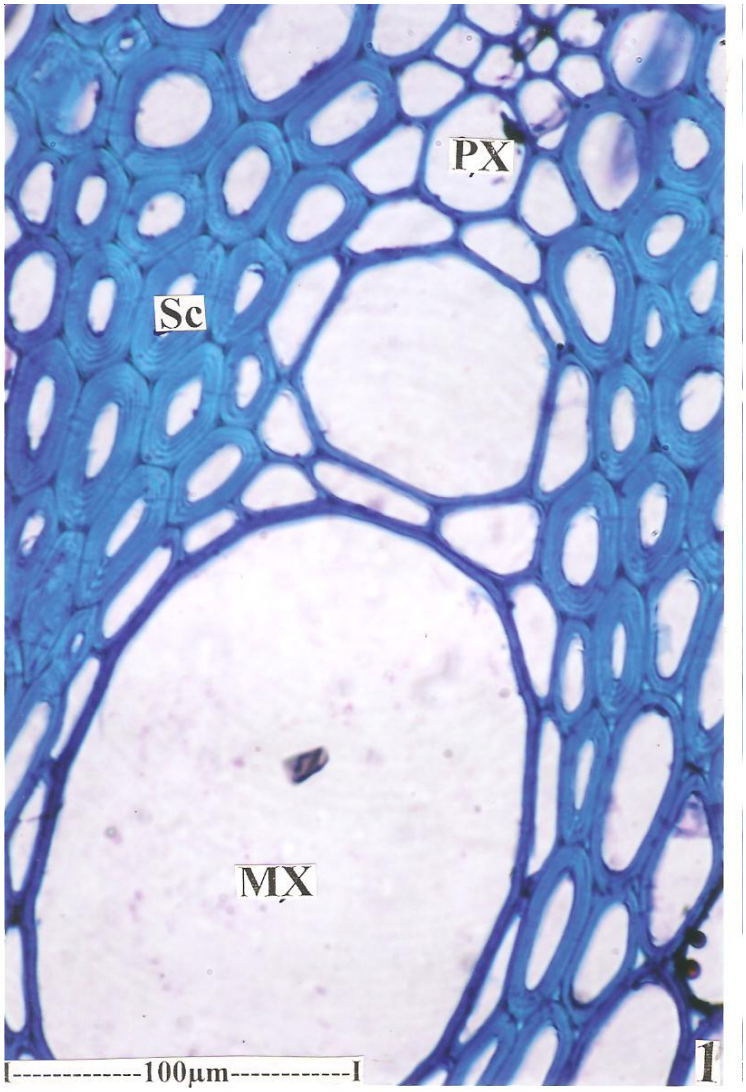


Fig. 4.2.1.3.1 A single exarch xylem strand – Enlarged

Sc – Sclerenchyma Mx – Metaxylem PX - Protoxylem

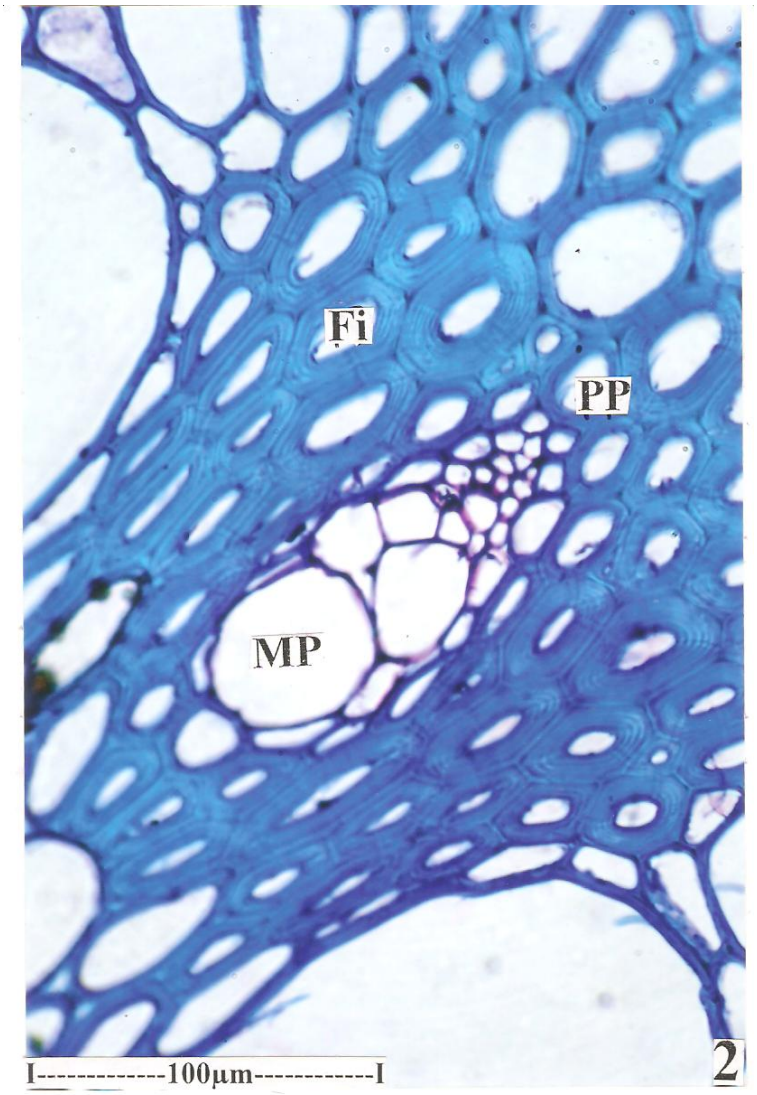


Fig.4.2.1.3.2 Exarch phloem strand – Enlarged

Fi - Fissure

MP - Metaphloem

PP – Protophloem

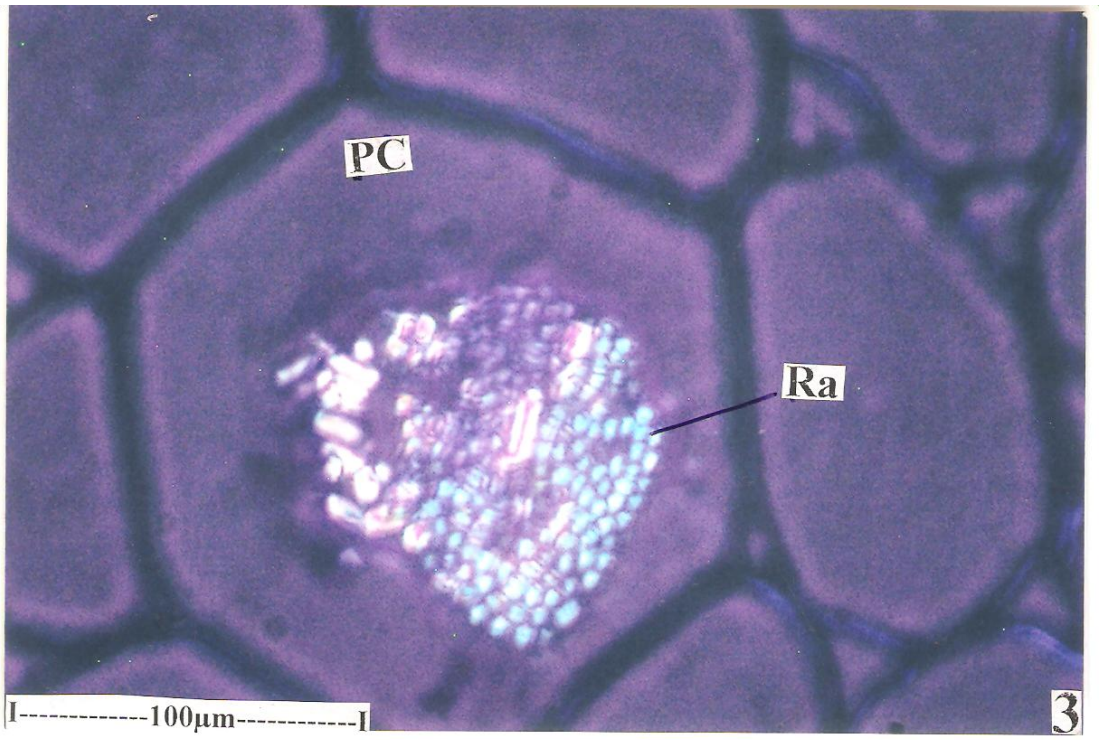


Fig.4.2.1. 3.3 Raphide type of crystal seen in cross sectional view within pith parenchyma

PC - Pithcell

Ra - Raphides

4.2.2.1. PHYSICO-CHEMICAL ANALYSIS:

S.No	Parameter	Mean Value
1.	Loss on Drying at 105°C	6.196 %
2.	Total Ash	3.373 %
3.	Acid insoluble Ash	1.025 %
4.	Water Soluble Extractive	4.6 %
5.	Alcohol Soluble Extractive	5.3 %
6.	Particle size	Completely passes through sieve no.44
7.	pH	6.5

TLC

Fig 4.2.2.2 After spray with visualizing agent

4.2.2.2 TLC Rf value

Sl.No	After Dipping in Vanillin-Sulphuric acid	
	Rf value	**Colour of the spot**
1	0.22	Purple
2	0.31	Purple
3	0.38	Purple
4	0.44	Yellow
5	0.47	Purple
6	0.64	Brownish yellow
7	0.69	Violet
8	0.77	Yellow
11	0.82	Purple
12	0.98	Brown

4.2.3. Qualitative phytochemical Analysis

Table4.2. 3: Showing the phytochemical analysis of *Karuvilanchi ver chooranam*

Qualitative Phytochemical Tests		
1.	Alkaloids	+ ve
2.	Anthraquinones	- ve
3.	Flavonoids	+ ve
4.	Triterpenes	+ ve
5.	Steroids	+ ve
6.	Phenol	+ ve
7.	Saponin	+ ve
8.	Tannin	+ ve
9.	Coumarin	- ve
10.	Cardiac glycosides	- ve

The qualitative analyses of *Karuvilanchi ver chooranam* was carried out in both dry and wet samples. From the test results alkaloids, flavonoids, tannins, triterpenes, Steroids, Saponins, phenolic Compounds were revealed to be present, whereas Cardiac glycosides, anthroquinones, coumarin were reported to be absent. (Table 3)

- Flavonoids have anti oxidant activity along with tannins and phenols.
- The presence of Steroids and flavanoids indicates the anti inflammatory and analgesic activity.

It is these secondary metabolites which can have therapeutic actions in humans and which can be refined to produce drugs.

4.2.2.3. SCANNING ELECTRON MICROSCOPE (SEM):

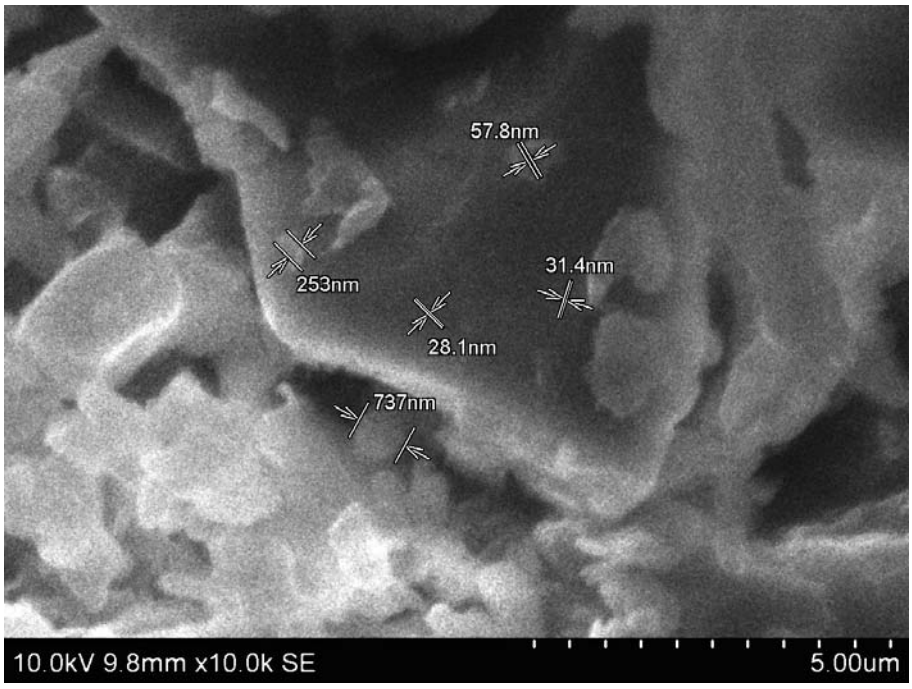


Fig.4.2.2.3. SEM

RESULTS:

SEM picture shows size of the sample is in Nano particle (Micro level).

The aims for nanoparticle entrapment of drugs are enhanced delivery to, or uptake by, target cells and/or a reduction in the toxicity of the free drug to non-target organs. These situations increase the therapeutic index, the margin between the doses resulting in a therapeutic efficacy but toxicity to other organs occur. So, creation of long-lived and target-specific nanoparticles is needed.

4.2.2.4 FTIR RESULTS:

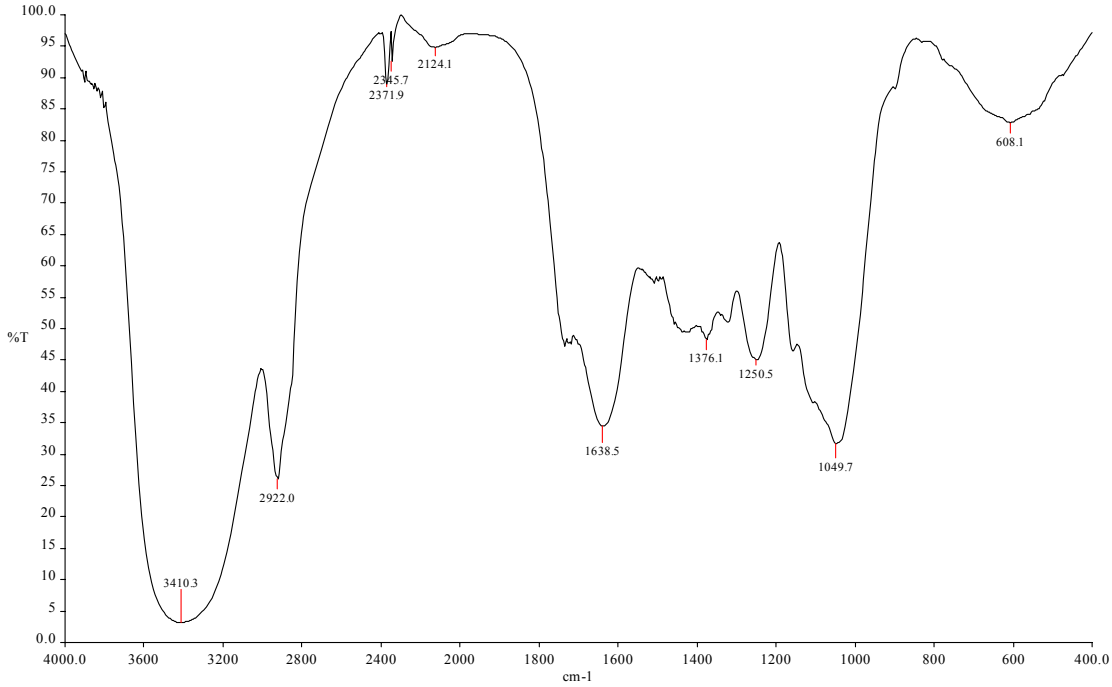


Fig.4.2.2.4 FTIR graph

4.2.2.4 FTIR results

Frequency bands	Functional Group
3410.3	Alcohol/Phenol O-H Stretch
2922.0	Carboxylic Acid O-H Stretch
2371.9	Phosphonates
2345.7	Phosphonates
2124.1	Alkynyl C≡C Stretch
1638.5	Aromatic C=C Bending
1376.1	Alkyl –methyl
1250.5	Trifluromethyl fluoroalkanes
1049.7	Fluoroalkanes ordinary
608.1	Chloroalkanes

4.2.4. CHEMICAL ANALYSIS OF *KARUVILANCHI VER CHOORANAM*:

RESULTS:

The Chemical analysis of *Karuvilanchi ver Chooranam* showed the following chemicals,

- **Proteins**
- **Starch**
- **Alkaloids**
- **Tannic acid**
- **Iron**

4.3. TOXICITY STUDY

Using acute toxicity study in mice the non-toxic effect of *Karuvilanchi ver chooranam* in mice was confirmed and the safety of the drug was ensured upto 5g/kg upon oral administration. Hence the therapeutic dose was finalized as 250 and 500mg/kg as per the standard reference.

Table 4.3.1: Dose finding experiment and its behavioral Signs of Toxicity

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	1000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.	2000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3.	5000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

1. Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhoea 18. Writhing 19. Respiration 20. Mortality

4.4. PHARMACOLOGICAL STUDY:

4.4.1. ANTI INFLAMMATORY AND ANALGESIC ACTIVITY

The result of the analgesic activity evaluated using hot plate method revealed that the reaction time for mice was significantly increased in a dose dependent manner after one hour of oral administration. The effect of *Karuvilanchi ver chooranam* on the writhing response in mice is shown in Table 4.4.2. It was found that both *Karuvilanchi ver chooranam* and Aspirin caused an inhibition on the writhing response induced by acetic acid. Doses of 250 and 500 mg/kg of the *Karuvilanchi ver chooranam* and aspirin respectively, could completely block the writhing response exhibited about 61.51 and 72.51% inhibition. Acetic acid, which is used as an inducer for writhing syndrome, causes algesia by liberation of endogenous substances, which then excite the pain nerve endings. The *Karuvilanchi ver chooranam* was found to exert a significant inhibitory activity on writhing response in dose range of 500 mg/kg.

The results obtained rather suggest that *Karuvilanchi ver chooranam* posses an antinociceptive activity and the mode of action might involve a peripheral mechanism. However, the central mechanism also might be involved. Formalin induced hind paw oedema is the standard experimental model of acute inflammation. The antiinflammatory action of the drug *Karuvilanchi ver chooranamwas* found to be moderately effective in the animal model. In acute inflammation model, the formalin induced paw oedema was significantly reduced by all the doses used when compared to control ($P<0.05$). Pain and inflammation are essential prelude to repair process. The mechanism of antiinflammatory action of *Karuvilanchi ver chooranam* may be related with the inhibition of prostaglandin biosynthesis enzymes such as lipooxygenase and cyclooxygenase, increased vascular permeability and inhibition of degranulation of mast cells.

Hence, the drug used for the trial proved to be a better alternative for the commercially available allopathic drugs. The inhibitory effect of the standard drug aspirin at a dose of 100mg/kg showed an average reduction of 33.33%. The results of the present investigation suggest that *Karuvilanchi ver chooranam* have significant anti-inflammatory effect against formalin induced paw oedema. *Karuvilanchi ver chooranam* indicated good pharmacological action and hence deserving detailed Investigation for other pharmacodynamic effects.

Table 4.4.1: Effect of *Karuvilanchi ver chooranam* on pain induced by hot plate method

Treatment	Dose	Reaction time in sec. before drug	% increase in reaction time after drug treatment		
			30min	60min	120min
Saline	3ml/kg	2.8±0.05	12.4±0.04	13.2±0.4	14.10±0.5
Karuvilanchi ver chooranam	250mg/kg	3.0±0.04	22.2±0.36**	28.23±1.12**	32.24±2.11**
Karuvilanchi ver chooranam	500mg/kg	2.8±0.05	36.1±0.40**	44.29±1.20**	47.02±2.24**
Pentazocine	5mg/kg	3.1±0.14*	66.22±1.28**	68.17±2.00**	67.34±1.82**

Values expressed in mean ±SEM and units in seconds, Significant *p<0.05, **P<0.01 (n=6)

Table 4.4.2 Effect of *Karuvilanchi ver chooranam* on writhing response in mice

Experiment	Number of writhes	Inhibition (%)
Control	38.2±7.3	-----
KVC 250 mg/kg	14.7±5.0*	61.51
KVC 500 mg/kg	10.5±4.8**	72.51
Aspirin 150 mg/kg	6.3±2.4**	83.50

Values are expressed as Mean±S.E.M. Drug and test compounds were given orally 30 min before 0.3% acetic acid injection. *P<0.05; significantly different from the control group (N=6).

Table 4.4.3 Effect of *Karuvilanchi ver chooranam* on formalin-induced edema in hind Paw of rats

S.No	Treatment	Dose (mg/kg)	Mean increase in paw volume	Percentage inhibition
1.	Control	5ml/kg	0.42±0.44	----
2.	*Karuvilanchi ver chooranam*	250mg/kg	0.37±0.61*	11.90
3.	*Karuvilanchi ver chooranam*	500mg/kg	0.35±0.62**	16.66
4.	Acetyl salicylic acid	100mg/kg	0.28±0.64**	33.33

Values expressed in mean ±SEM, Significant *P<0.05; **P<0.01 compared to control

6. CONCLUSION

The trial drug "*Karuvilanchi ver Chooranam*" has been selected and its efficacy was analyzed in the treatment of Osteoarthritis.

The plant is readily available and preparation is also simple.

The trial drug is not only efficient, but also cost effective.

The results of the present pharmacological study suggest that *Karuvilanchi ver chooranam* have significant anti-inflammatory effect against formalin induced paw oedema

The drug shows good Anti inflammatory and analgesic activity. During the entire clinical trial no adverse effects resulted.

From all the above observations, I conclude that the trial drug "*Karuvilanchi ver chooranam*" (*Smilax zeylanica,*) gives a new hope in the Osteoarthritis Treatment.

7. SUMMARY

The herb *Karuvilanchi ver* was collected from Kanyakumari (Dt), Tamil Nadu and it is then purified, powered and stored. This drug was subjected to different studies by the author.

"*Karuvilanchi ver Chooranam*" was selected for this dessertation study to evaluate the Anti inflammatory and analgesic activity, and also to prove its efficacy and safety in Osteoarthritis.

The information about the drug, was collected from various text books, Literature were referred. From these informations, the author came to an idea about the drug and its efficacy on Osteoarthritis.

A brief description about botanical aspect of the herb *Karuvilanchi ver* and its identifying characters and phytochemical analysis reports were given.

The pharmacological analysis revealed that the drug has got significant Anti inflammatory and analgesic activity.

In clinical study, the drug has showed remarkable improvement in 78% of cases.

The patients responded well from the commencement of the treatment and there were no adverse effects during the course of the clinical trial.

This present study suggests that *Karuvilanchi ver Chooranam* has the significant medicinal value against the disease osteoarthritis without any adverse effect.

1. INTRODUCTION

"Science without religion is blind
And religion without science is lame"

- Albert Einstein

Based on the ancient Tamil literatures, '*Tholkappiyam and Silappathikaram'* the siddha system of medicine flourished in the first Tamil sangam period [sixth century B.C].In *Tholkappiyam* the siddhars were introduced as *'arivar'* in the quotation,

"மறுவில் செய்தி மூவகைக் காலமும்
நெறியின் ஆற்றிய அறிவன் தேயமும்"

- *Tholkappiyam – purathinai iyal 74*

Ilampooranaar has written the meaning for the above said quotation as,

"குற்றமற்ற செயலையுடைய மழையும்
பனியும் வெயிலுமாகிய மூவகைக்
காலத்தினையும் நெறியினாற் பொறுத்த
அறிவன் பக்கமும்"

Siddhars were great doctors of medicine, philosophers, and men with deep knowledge of anatomy and chemistry noted for their wide travel, simple living and high thinking. They were the pioneers in the use of metals and minerals in the treatment of various diseases.

In Siddha, diseases are diagnosed mainly with the help of signs and symptoms of the diseases. Other factors that also help to diagnose diseases are touch, examining the pulse, tongue, colour, speech, eyes, faeces and urine. The main aim of Siddha system of medicine is to assure a healthy life which includes both physical and mental health to man kind. A siddhar is one who has attained siddhi, i.e. "power, prowess, strength, ability", a special kind of psychic and supernatural, miraculous, occult power. There are 8 kinds of super natural powers called as "Ashtama Siddhis". The materials used by siddhars, as drugs could be classified into herbal products *[thavaram],* inorganic substances & *navamanigal [thathu]* and animal products *[jangamam]*. The *thathu*

products are further classified into *logham*, mercurial compounds, *pashanam, karasaram and uparasaam*.

Diuretics are medicines that aid the elimination of sodium (salt) and water from the body.

A diuretic provides a means of forced diuresis which elevates the rate of urination. There are several categories of diuretics. All diuretics increase the excretion of water from bodies. When the kidneys excrete sodium, they excrete water from the blood along with it that decreases the amount of fluid flowing through the blood vessels, which reduces pressure on the walls of the arteries.

In modern medicine, diuretics are used to treat heart failure, liver cirrhosis, hypertension and certain kidney diseases Up to one in three heart-failure patients who take diuretic drugs experience diuretic resistance**:** when the process of eliminating excess sodium and water stops before enough fluid has been removed from the patient's body.

The main adverse effects of diuretics in modern medicine are hypovolemia, hypokalemia, hyperkalemia, hyponatremia, metabolic alkalosis, metabolic acidosis and hyperuricemia. So, there is a need for more effective and less toxic diuretic.

"Chendooram" is a category of medicine with reddish colour and powdery form unlike in the ayurvedic system, where 'sindoora' cotain mercury and sulphur as a rule and involve heating to get a sublimate,

The 'chendooram' in siddha system need not necessarily contain sulphur or mercury and there are instances where no heating is required at all in the processing.

Thus, atleast 5 different modes of preparation of 'chendooram' are present.

They are

1. *'Chendooram'* prepared without heating. [*araippu chendooram*]
2. '*Chendooram*' prepared by open heating [*erippu or varuppu chendooram*]
3. '*Chendooram*' prepared by capsule heating [*puda chendooram*
4. '*Chendooram*' prepared by sand bath process [*kuppi erippu chendooram*]
5. '*Chendooram'* prepared by applying heat in the range close to 100ºc [*laghu puda chendooram]*

Chendoorams are special medicine in siddha system and they are said to retain their potency for 75 years. The speciality of *chendoorams* can be understood by the books like *'agathiyar chendooram 300'*.

'Jala manjari chendooram' is one of the *erippu chendooram* in siddha system which is written by the great *siddhar yoogi muni* in '*Yoogi Karisal 151'* indicated for anemia, edema etc., the name *Jalamanjari,* ' *jala'* means water, which itself indicates the diuretic action of the drug. Although many herbs are available as diuretics, the use of *jalamanjari chendooram* is justified by the fact that the herbs are available only in seasons, but does not occur throughout the year.

The trial drug '*Jala manjari chendooram'* will be clinically given for the patients with urolithiasis, edema, ascites and hypertension as these diseases can be treated well with diuretics.

The shelf life period of this drug is very long it will be available throughout the year. So I am interested to scientifically validate this trial drug '*Jalamanjari Chendooram'*,

2. AIM AND OBJECTIVES

The Aim of the Study is to prove the efficacy of the *'Jalamanjari chendooram'* for Diuretic activity. Diuretics are necessary for treatment in conditions like Oedema, Hypertension, and Renal calculus.

Synthetic Diuretics such as Loop Diuretics [Frusemide] and Thiazide like Diuretics accomplish the demand but cannot be used for long term as they produce decrease in concentration of electrolytes which in turn results in serious conditions. Diuretics like loop diuretics, thiazides are synthetics in nature and they do not contain any active constituents, nutrients or any other medicinal or tonic properties to mankind.

'Jalamanjari chendooram' is a drug which offers actions of elimination of excess body fluids as in oedema, ascites etc which is indicated in the literature.

Hence the Aim of the Study is to prove the safety and efficacy of the *'Jalamanjari chendooram'* for Diuretic activity.

Objectives

The objectives are

The drug was studied in the following aspects.

1. Literature reviews.
2. Chemical Analysis of *'Jalamanjari chendooram'*
3. Toxicity study.
4. Pharmacological activity.
    - Diuretic activity.
5. Clinical study.
6. Statistical analysis of the results.

3. REVIEW OF LITERATURE

3.1. MATERIA MEDICA ASPECT

Vennkaaram

General Properties

"சொறிபுடையெண் குன்மநமை சோரி யாசம்
பறிகிரகணி கல்லானம் பன்னோய் - நெறியைத்
தடங்கணங்க பங்கிருமி சர்ப்பவிடஞ் சந்நி
யிடங்கணங்க லக்கிற்போ மெண்."

Venkaaram is indicated for Toad skin, carbuncle, gastric ulcer, itching, haemorrhoids, hemiplegia, dental disease, urinary tract infections, kapha, veneral ulcer with pus, poison due to snake etc., delirium, infective disease, abdominal disease, cough,. It is also indicated for indigestion, rhinitis, delayed labour, amenorrhoea, dysmenorrhoea, hemorrhagia, sinusitis, stomatitis, ulcer on the nipple, anemia due to menorrhagia, epilepsy, uterus contraction in slow delivery.

Uses

- Roasted Borax (650mg – 1300mg) is given with tender coconut water for Urinary tract infections.
- Borax mixed with water may be used as an irritation solution for bladder wash in case of urethritis.
- Borax 325mg – 975mg is given for Ascites.

Ayam

General Properties

"பாண்டுவெண் குட்டம் பருந்தூல நோய்சோபை
மாண்டிடச்செய் மந்தங்கா மாலைகுன்மம் பூண்ட
பெருந்தாது நட்டமும்போம் பேதிபசி யுண்டாங்
கருந்தாது நட்டமிடுங் கால்"

Iron preparations are used in treating the disease like anemia, jaundice, leucoderma, obesity, dropsy, anorexia, peptic ulcer, spermatorrhoea, diarrhoea and dyspepsia.

Uses

- *Aya parpam* is indicated for
    - Ascites (*peruvayiru*) in adjuvant *Piper longum* oil or its rasam.
    - Anuria in adjuvant breast milk.

Kaantham

General Properties

“காந்தத்தாற் சோபைகுன்மங் காமிலமே கம்பாண்டு
சேர்ந்ததிரி தோடவெட்டை சீதங்கால் - ஓய்ந்தபசி
பேருதரங் கண்ணோய் பிரமியநீ ராமையும்போம்
ஓரினிறை யாயுளுறும் உன்”

Kaantham is indicated for swelling, peptic ulcer, Jaundice, Gonorrhoea, Dropsy, Disorders of three humours, leucorrhoea, cold, Rheumatic disorders, Dyspepsia, Anasarca, Eye disease and spleenic tumor. It also increases the life span.

Uses

- Kaantha parpam with adjuvant
  - pure water is indicated for Vatha and associated illness such as Ascites, Abdominal Distension etc,
  - Garlic oil is indicated for kapha and associated illness such as Oliguria (Neerkattu).

Ganthakam

Nellikkai ganthakam

(Gooseberry sulphur)

“நெல்லிக்காய் கந்திக்கு நீள்பதினெண் குட்டமந்தம்
வல்லை கவிசைகுன்ம வாயுகண்ணோய் - பொல்லா
விடக்கடிவன் மேகநோய் வீறுசுரம் பேதி
திடக்கிரக ணிகபம்போந் தேர்”

- This is considered to be useful in the treatment of 18 types of skin diseases, liver enlargement, abdominal distension, eye diseases, chronic venereal diseases, chronic diarrhoeas, Gastric ulcer, poisonous bites, fever due to *vatha,* chronic dysentery etc.

Vaana ganthakam

(Stick sulphur)

- This sulphur is useful to control the pathogenic micro organisms in the blood. It is also useful in the treatment of chronic joint disorders, scabies, asthma , heart attack, cough ,anorectal diseases, leprosy etc.

  Uses

  - Ganthaka parpam is indiated for ascites with adjuvant butter milk.

- Ganthaka chendooram prepared using the juice of Indian aloes in the dose of 130 – 260 mg will be useful in the treatment of abdominal distension etc.
- Ganthaka rasayanam

  Dose: 1.3 to 1.9 gram
  - Is useful in the treatment of dysuria and swellings

Navacharam

General properties

"குன்மம் குடற்சூலை கொல்லும் மகோதரத்தை
வன்மையுறு கல்லடைப்பை மாற்றுங்காண் - சன்மக்
கவிச்சுமுத் தோடங் கனவாத நீக்கும்
நவச்சார மாதே நவில்"

Navacharam cures abdominal pain, distended abdomen, urinary calculus, bad odour in the skin, sinusitis, amenorrhoea, whooping cough, intermittent fever, three humours, indigestion, hepatomegaly, hepatitis, spleenomegaly, rhinitis, tuberculosis, haematemesis, and facial paralysis.

Uses

- The salt may be added to 500ml of boiled rice gruel and may be taken in little by little for treatment of leucorrhoea, blood disorder, chronic dysentery, bronchitis and disease of stomach and urinary bladder.
- The salt dissolved in the decoction of *Hygrophila auriculata* may act as a diuretic and may be effective in the treatment of jaundice, liver enlargement and spleenomegaly.
- Ammonium chloride is dissolved in water. A cloth is soaked in the solution and applied over the disease affected part. Its indications are swelling. Hepatitis, abdominal tumour, an inflammation of the lymphatic gland etc.

Cheenakaram

General properties

"சீனமெனுங் காரமது சீறிவரு பல்லரணை
ஆனைக்கால் கண்ணோய் அனிலமொடு – மாநிலத்தில்
துன்மாங் கிசம்வாயு தோலாத உள்ளழலை
குன்மமிவை போக்குமெனக் கூறு"

It cures gingivitis, eye diseases, Elephantiasis, *Vayu*, tumour, heat, gastric ulcer, hypertension, haemorrhage, Dysentry, diarrhoea, children's vomitting, Whooping cough, cough with expectoration, pharyngitis, Menorrhagia and Gonorrhoea.

Uses

- Padikara Parpam :

  Dose: 130 – 520 mg

  Adjuvant: cow's butter, juices of *Aerva lanata (chiru peelai), Tribulus terrestris (chiru Nerunjil)*

  Curable diseases: absolute suppression of urine, dysuria, stricture of urethra.

Vediyuppu

General properties

"மல்லாறும் மட்டகுன்ம மாதருதரக் கட்டி
கல்லா மதைப்புநீர்க் கட்டருக – லெல்லாமே
கம்பிகம்பி யென்றுங் கருவுண்டா மங்கிநின்ற
கம்பிகம்பி யென்றுரைக்குங் கால்"

The salt is useful in the treatment of 8 types of Gunmam, uterus fibroids, Anorexia, Urinary tract infections, dysuria, Stranguary, Ascites, Menopaused disorders, abdominal distension and Asthma. It improves fertility in women.

Properties:

Potassium Nitrate Salt has got

- Demulcent
- *Diuretic &*
- Diaphoretic properties.

Gomoothira silasathu

General properties

"கோமூத் திரசிலா சத்தாற் குறுகியே
போமூத் திரமெரிவுட் புண்மேகம் - நாமேவு
வெப்புதிர வெப்புமறும் வீழிமுனி விம்பந்
துப்புமஞ்சு மெல்லிதழாய் சொல்"

The asphaltum may be effective in burning micturition , ulcers of the urinary tract, Gonorrhoea, ulceration of the tongue and hypertension.

Uses

- It is also effective in asthma, tuberculosis, diseases of the intestine, sterility, *vatha* disease, swellings and ulcers, urinary tract infections, dysmenrrhoea and rheumatism. This is also effective in rapid union of fractured bones. It removes calculus in the urinary and gall bladders. It is also useful in skin diseases.
- For the abscesses developed due to kapha and pitha fevers, the *gomoothira silasathu* is given with the decoction of cotton seeds or coriander seeds for 4 to 5 days. It may also be given for spleenomegaly.
- The *gomoothira silasathu* (65mg) sticks prepared with wheat flour is inserted into the urethra for curing the urinary diseases.
- For delirium and inflammation of the urethra, the *gomoothira silasathu* (65mg) is mixed with cow's milk (raw) and given.

Kalnar

General properties

"காசபித்தம் வாதங் கடுப்பீறு நோயெரிவு
வீசுசர்த்தி நீரடைப்பு விந்துநட்டம் - பேசுமசை
தின்னாரை கூவுமந்தந் தீக்குடர்க்கால் தாகமிவை
கன்னாரைக் கூவவிடுங் காண்"

It is indicated for rheumatism, disease of teeth, gingivitis, urethritis, urinary retention, bilious vomiting, dysuria, spermatorrhoea, indigestion, hernia, thirst etc.

Uses

- Asbestos has got diuretic and bitter properties.
- *Kalnar parpam* is taken along with ghee or butter at a dose of 260 – 520mg is effective in burning micturition, urinary retention and spermatorrhoea.

Karpoora silasathu

General properties

"கல்லடைப்பு மேகங் கனதூலம் வித்திரதி
சொல்லடைக்கு நீரருகற் சோணிதக்கான் - மெல்லிடையார்க்
கில்லகச்சத் தில்லையெனு மிந்திரிய நட்டமுமாங்
கல்லகச்சத் தில்லையெனுங் கால்"

Karpoora silasathu is useful in the treatment of vesicle calculus, gonorrhoea, and abscess with pus, strangury, articular rheumatism and spermatorrhoea.

Uses

- *Silasathu* also cures gonorrhea, internal ulcers, hypertension, *kapha* disease, chronic cough and dysentery.
- *Karpoora silasathu parpam* prepared using the juice of *Molllugo lotoides* is given with cow's butter for burning sensation of the skin and dysuria.
- *Karpoora silasathu parpam* prepared by adding borax is used for curing vesicle calculus in the urinary tract.

Kavikkal

General properties

"அடலறு நற்காவிக்க லட்சிநோய் மேகம்
வெடியக்கி வாந்தி பித்தம் வீட்டும்"

Kavikkal may be useful in the treatment of eye disease, venereal disease, vomiting and extensive eczema.

Uses

- Red ochre has got astringent taste and cool potency. It controls excessive bleeding – anti coagulant.
- *Poonkavi chendooram*
  Dosage: 650 mg
    - With suitable adjuvants is used for the treatment of diarrhoea with *bleeding, haemorragia and vomiting.*

Sangu

General properties

"கசிவா மிரத்த பித்தங கண்ணோய்க ளேகும்
பசியாறும் வாதம் பறக்கு- மிசிவுடனே
தங்கு முளைவிரணந் தானகலு மேவெள்ளைச்
சங்கமது வுண்டாயிநற்றான்"

It is useful in the treatment of hypertension, eye diseases, *vatha* diseases etc.

Uses

- The conch has body strengthening, deflatulant, and appetite stimulant, bitter and mucolytic properties.
- Sangu parpam prepared using juice of *Phyllanthus emblica* is indicated for urinary tract infections.
- Sangu parpam prepared using the whole plant juice of *Tabenaemontana divaricata (Nanthiyavattam)* is indicated for ascites in adjuvant honey

Table 3.1 Other diuretic preparations in siddha literatures

Constituents	Name of the drug	Reference book
• Vediyuppu • Venkaaram • Karpoora silasathu • Cheenakaram	Vediyuppathi chunnam	Anubogavaidya navaneedham part 3
• Venkaaram • Karpoora silasathu • Kalnaar • Navacharam	Venkaara parpam	Anubogavaidya navaneedham part 3
• Vediyuppu • Venkaaram • Kalnaar • Cheenakaram	Cheenalavana parpam	Kannusamyparambarai vaithiyam
• Vediyuppu	Neeradaippu neer	Pulippani vaaithiyam 500
• Vediyuppu • Cheenakaram • Navacharam	Vediyuppu jeyaneer	Anubogavaidya navaneedham part 3
• Vediyuppu • Cheenakaram • Navacharam	Padikara parpam	Anubogavaidya navaneedham part 3
• Vediyuppu • Ganthakam • Sangu	Vediyuppathi chendooram	Anubogavaidya navaneedham part 3
• Vediyuppu • Ganthakam	Villaiuppu	Anubogavaidya navaneedham part 3
• Vediyuppu • Venkaaram	Venkara chendooram	Anubogavaidya navaneedham part 3

Constituents	Name of the drug	Reference book
• Vediyuppu • Venkaaram	Kara vediyuppu parpam	Kannusamyparambarai vaithiyam
• Vediyuppu • Navacharam	Navachara kattu	Anubogavaidya navaneedham part 3
• Vediyuppu • Navacharam	Vediyuppu chunnam	Kannusamyparambarai vaithiyam
• Karpoora silasathu	Pavala silasathu parpam	Kannusamyparambarai vaithiyam
• Sangu	Vellai sangu parpam	Kannusamyparambarai vaithiyam
• Kalnaar	Naattu kalnar parpam	Kannusamyparambarai vaithiyam

3.2. MODERN ASPECT

Potassium Nitrate *(Vediyuppu)*

- Potassium nitrate in solution is a refrigerant, efficient diuretic and diaphoretic,
- It acts on the vascular system and thus reduces the frequency of the pulse.
- Given in the solid form or in concentrated solution it acts as irritant. In weak solutions, it is an excellent refrigerant drink in fevers with hot and dry skin, parched tongue, with great thirst and scanty and high colored urine.
- It is useful also in the early stages of dropsy, in cases of small pox, measles, influenza, catarrh, gonorrhea, and acute rheumatism, bleeding from the lungs, stomach, uterus or other internal organs attended by fever.
- A mixture of nitre 2 parts and leaf juice of the Radish 1 part is given in doses of 80 grains to relieve scalding and retention of urine, also suppression or scantiness of urine.

Asphaltum *(Silasathu)*

- **Source**:

  Ejected out of rocks during hot weather in the lower Himalayas, Vindhya, and other mountain tracks and Nepal where iron abounds, naturally flowing out from between the fissures in the rocks; or it may be a tar formed in the earth from the decomposition of vegetable substances.
- *Silajit i*s of a bitter taste and of a smell resembling cow's stale urine. This is known as *gomuthra silajit.*
- The other variety found in the bazaars is called *Karpoora Silajit* which occurs in white plates.
- The black variety is the one mostly used in medicine after purifying it by certain processes.
- **Action**:

  Locally,
  - Antiseptic
  - Anodyne
  - Parasiticide and
  - Antiphlogistic.

  Internally,
  - Alterative
  - Tonic

- Slightly laxative
- Cholagogue
- Respiratory stimulant
- Disinfectant
- Expectorant
- Intestinal antiseptic
- Diuretic and
- Lithontriptic

Uses:

- Charaka says "There is hardly any curable disease which cannot be controlled or cured with the aid of *Silajit"*.
- It is specially employed in genito – urinary diseases and in diabetes; in gall stones, jaundice, enlarged spleen, fermentative dyspepsia, worms, digestive troubles, piles, adiposity, anasarca, renal stone, renal and bladder calculi, anuria etc., hysteria, neurasthenia, epilepsy and insanity nervous diseases; amenorrhoea, dysmenorrhoea and mennorrhagia; scrofula, tuberculosis, phthisis and leprosy; eczema , elephantiasis, anaemia, anorexia , biliary congestion, chronic bronchitis, asthma, fracture of bones etc.,
- It is also useful in ascites, uraemia, cholaemia and the like. It is valuable in cases of diabetic albuminria, where both casts and albumin diminish;
- The indigenous practitioners also used *silajit* as a diuretic and lithontriptic.
- In the first stage of ascites it is used with iron – rust together with milk diet; salt and water is stopped altogether.
- In strangury or painful micturition *Silajit* is used with other diuretics and demulcents like the decoction of *Tribulus terrestris, Glycyrrhiza glabra* etc.
- In albuminuria and chyluria it is beneficial with the decoction of astringents like catechu, *Shorea robusta*, juice of leaves of *Cajanus indicus* or of garlic.

Ferrum (Ayam)

- **Source**:

  Rarely free in nature, though very widely distributed in both the organic and inorganic kingdoms. Found in nearly all rocks, soils, etc. variously combined with oxygen as haematite, magnetic iron ore etc., with sulphur as iron – pyrites; in the ashes of plants and even the blood of animals; also in the bile , chyle, gastric juice, lymph , milk , pigment of the eye and in the urine.

- **Action**
  - Iron improves the quality of blood. Iron produces constipation and that is why it was recommended to be administered with *Triphala powder.* Iron stimulates the functional activity of all the organs of the body and is therefore a valuable general tonic.

- **Uses**:
  - Iron and its preparations are generally given with selected vehicles. In consumption it is given with black pepper and long pepper.
  - In haemorrhagic diseases such as haemoptysis, haematuria, bleeding from piles etc., iron is commonly given with good results.
  - Iron is a valuable remedy in Bright's disease and not cures the anaemia but also lessens the albumin.
  - Dr.H.C.Sen says "recent investigations have shown that iron in its mineral state is not absorbed. The only way in which it enters the system is as vegetable or mineral compound.
  - For chronic fever, anaemia, jaundice etc and urinary diseases as gonorrhea, strangury etc., a preparation called *Mehamudgara rasa* is recommended.
  - In diabetes and other urinary diseases, female complaints etc., pills called *Virhat Somanatha rasa* are recommended to be administered with honey.

Sulphur (*Ganthakam*)

- **Source**:

  A non – metallic element found free in beds of gypsum and in a state of sublimation in regions of extinct volcanoes; also in combination with several ores called pyrites, as sulphates and sulphides of iron, copper, lead, zinc, mercury etc.,in India it occurs naturally in some parts, in Nepal, Kashmir, Afghanistan and in Burma.

- **Action**:

  Sulphur is described as of bitter astringent taste with a peculiar strong smell. It increases bile, acts as a laxative and alterative and its preparations also act as alterative, laxative, diuretic and insecticide. Sulphur when taken internally and in small doses, becomes absorbed and may be detected in the sweat, milk and urine. It is a stimulant to the secreting organs such as the skin and the bronchial mucous membranes. It has a specific action on the rectum and increases the haemorrhoidal secretions. The sulphurous and mineral waters as they contain earthy and alkaline sulphates act as a laxative and diuretic, while the sulphurous acid disengaged from them acts as a diaphoretic. In large doses it acts as a purgative.

- **Uses**:

  - In combination with mercury it is used in almost all diseases. It readily combines with and fixes metallic mercury and is therefore extensively used in combination with that metal.
  - Sulphur is useful in cough, asthma, consumption and general debility; also in enlargement of the liver and spleen, chronic fevers etc.
  - For tympanitis, colic, ascites etc., a drastic purgative named *Mahanarcha rasa* is given with cold water.

Sodii Biboras *(Venkaaram)*

- **Source**:

  It occurs as a natural deposit. Crude borax is found in masses by evaporation of water, on shores of dried up lakes in India and Tibet; it is also obtained from themud of lakes surrounded by hills in Nepal. When purified by dissolving it in water, straining through cloth, evaporating to dryness and crystallizing, it is called borax.

- **Action**:
  - Diuretic
  - Emmenagogue
  - Astringent
  - Antacid and
  - Local sedative
  - Antiseptic

- **Uses**:
  - Borax is given internally in doses varying from 10 to 30 grains, in acidity of the stomach, amenorrhoea, dysmenorrhoea, menorrhagia, puerperal convulsions and to promote uterine pains during labour.
  - As a solvent it is given in uric acid diathesis with good results. Dose is from 20 to 40 grains for an adult.
  - In small doses it is given to children as a laxative. It is also used in loss of appetite; painful dyspepsia, cough, asthma and diarrhoea.

Alumen *(Padikaram*)

- **Source**:

  Chiefly found with peroxide of iron in Silajit or in Alum earths of Nepal or prepared from the alum shales in the Punjab, Rajputana, Bihar and Cutch States. As found in the bazaars, it is often mixed with impurities; it may be rendered fit for medicinal purposes by dissolving it in boiling water, straining the solution and evaporating it so as to obtain crystals, which should be preserved for use.

- **Action**:
  - Astringent
  - Caustic
  - Haemostatic
  - Antispasmodic and
  - Antiseptic;

- **Uses**:
    - It is useful in leucorrhoea, haematuria, haemoptysis, menorrhagia, gastric and intestinal catarrh and other haemorrhages;
    - In narcotic poisoning in children it is a good and efficient antidote.
    - In haemorrhages from kidneys, uterus and other internal organs alum in doses of 10 to 12 grains thrice daily with or without opium is given with benefit, but not when much fever is present.
    - Alum lotion internally is administered to check haemorrhage from lungs, stomach, kidneys and other organs or to arrest excessive menstrual flow.

Ammonium Chloride (*Navacharam*)

- As obtained in the bazaars is generally very impure in dirty white or brownish transclucent cakes, "as it is manufactured from a kind of clay found at Karnal in the Punjab" – (Chopra)
- It is obtained by the combustion of excretions of various animals or of animal matters or by burning coals or common salt. It is a secondary product in the manufacture of coal gas.
- It is generally obtained in India from unburnt extremities of brick kilns in which manure of animals, especially camel's dung is used as fuel. To this coal and common salt are added and sublimed. It is thus obtained in white granular crystals or transparent masses. It is readily soluble in water and is highly deliquescent. It has a saline, disaggreable, nauseous and pungent taste.

- **Action**:

    - Alterative
    - Expectorant and
    - Cholagogue in small doses.
    - Purgative in large doses.

- **Uses**:
    - In urinary diseases chiefly where the urine is full of lithates it is very useful.
    - As an alterative it acts by slowly modifying the nutrition of the tissues ; it is a useful agent in chronic inflammatory diseases of the glands such as

thyroid , liver and spleenand in induration of the uterus, ovaries and the prostate.

Silicate of Aluminia, Magnesia & Oxide of Iron *(Kavikkal)*

- It is a calcerous mineral often made into small cakes and stamped with certain impressions.
- It occurs in powder or irregular pieces of reddish brown or variegated colours. It is soft and somewhat and heavy.
- **Action**:
  - Refrigerant
  - Astringent
  - Absorbent and
  - Antiseptic

Uses:

- Dose is 5 to 30 grains. Internally the powder with cream is given in advance cases of dysentery.
- A paste made of it 2 parts, alum 4 and rose water 10 parts is given internally for scalding in the urine.
- Externally a paste of it is applied to inflamed and swollen glands, also to ulcers and raw surfaces.

Calcium

(Eng: lime)

Lime is obtained from conch shells (*Sangu)*

Uses:

- Lime is used internally in dyspepsia, enlarged spleen and other enlargements in the abdomen and externally as a caustic.
- As a caustic, lime is used as an application to enlarged glands and tumours.

Adjuvant:

Honey

Actions:

- Demulcent
- Laxative
- Astringent
- Antiseptic
- Expectorant
- Digestive
- Stomachic
- Sedative

Characters:

"ஐயிரும லீளைவிக்க லக்கிப்புண் வெப்புடல்நோய்
பைய வொழியும் பசியுமுறும்- வையகத்தி
லெண்ணுமிசை யாமருந்திற் கேற்ற வனுபான
நண்ணுமலைத் தேனொன்றி னால்".

- *Pathartha guna sinthamani*.

- Honey is a **good adjuvant** and also cures *kabam,* cough,etc.
- The honey has not only adjuvant action but also balances the three humors and maintains the good health condition of the body.

"அனுபான மாய்ப்பின் அவிழ்தமுமாய்த் தோன்றி
கனமான தேகநிலை காட்டிப்- பினுமே
யரசன் முதல்வோ ரையுமாட்டு வித்தாலே
பிரசத் தினாற்போம் பிணி".

3.3 SIDDHA ASPECT OF THE DISEASE

Siddha aspect of the disease:

Kalladaippu:

Synonym: *Achmari*

Definition:

This disease is characterized by intermittent cessation of urine during micturition, pain at the tip of the penis, burning micturition, backache and small pebbles found in the urine.

Aetiology:

- Drinking of stagnant water
- Carbohydrate diet
- Excess intake of vadha food

Classification:

It is classified into 4 types.They are

- *Vadha kalladaippu*
- *Pitha kalladaippu*
- *Kapha kalladaippu*
- *Mukkutra kalladaippu*

General symptoms:

- Frequency of urination
- Intermittent cessation of urine
- Pricking pain in penis
- Inflammation of penis
- Irritation of bladder and lower abdomen
- Haematuria

***Oothal noi**:*

Synonyms:

Thommai noi, Sokai noi, Sobai noi.

Definition:

This disease is characterized by anaemia and pallor, also the upper and lower extremities, face and abdomen distends against normal. This is called as '*oothal'* disease. Since the patient feels so grievance, this is called as '*sogai*'. Since anasarca is present, this disease is called *'veekam'*.

Aetiology:

"பாங்கான சன்னிபா தச்சுரங்கள்
பகர்சித்தப் பிரமைசன்னி பரவலாலும்
தேங்காங்ன பன்னாந் தீண்ட லாலும்
சில்விடங்கள் தேகத்தி லூற லாலும்
ஆங்கான சிறையிருத்த லடிபடுத லாலும்
அநேக வழி நடக்கை மலை யிருக்கை யாலுந்
தாங்கான சலக்கரைகள் தனலி லிருத்தல்
சாம்பல்மண் மாதவிடாய் சோபை யாமே."

- Follows anemia
- Toxicosis
- Food variants
- Dysfunctioning of paravukaal
- *Sittha pramai sanni*
- Snake bite
- Hilly residence
- Damp and marshy areas
- Pick's disease

Pre monitory symptoms:

- Emaciation
- Oedema
- Exhaustion
- Dyspnoea
- Headache

- Fainting
- Oedema of lower extremities, face and abdomen

Classification:

This is classified into 4 types. They are

- *Vadha oothal noi*
- *Pitha oothal noi*
- *Kapha oothal noi*
- *Mukktra oothal noi*

General symptoms:

"சோகையி னிலக்கணங்கேள்
சோர்வு கைகால் கட்குண்டாம்"

- Anorexia
- Exhaustion
- Hydrocele
- Thickness of the ear pinna
- Hearing impairment
- Squint
- Pallor
- Dyspnoea

3.4. MODERN ASPECT OF THE DISEASE.

Diuresis:

Diuresis means increased excretion of urine.

Diuretics

Diuretics are an indispensable group of therapeutic agents that are used to adjust the volume and /or composition of body fluids in a variety of clinical situations including hypertension, acute and chronic heart failure, acute and chronic renal failure, nephritic syndrome and cirrhosis.

The word "diuretic" comes from Greek word ‘dia-‘=thoroughly + ‘ourein’ =to urinate so diuretic means to urinate thoroughly.

Table 3.4.1 Classification of diuretics

1. High efficacy diuretics (lnhibitors of Na-K- 2Cl- cotransport)	- *Sulfamoyl derivatives* Furosemide, Bumetanide, Torasemide
2. Medium efficacy diuretics (lnhibitors of Na-Cl- symport) (A) *Benzothiadiazines (thiazides)*	Hydrochlorothiazide, Benzthiazide, Hydroflumethiazide, Clopamide
(B) Thiazide like (related heterocyclics)	Chlorthalidone, Metolazone, Xipamide, Indapamide.
3. Weak or adjunctive diuretics *(a) Carbonic anhydrase inhibitors*	Acetazolamide
(b) Potassium sparing diuretics	i) Aldosterone antagonist: Spironolactone (ii) Inhibitors of renal epithelial Na+ channel: Triamterene, Amiloride.
(c) Osmotic diuretics	Mannitol, Isosorbide, Glycerol

Mechanism and uses of diuretics

High ceiling diuretics

- inhibit the Na-K-2Cl symporter
- **Uses**
  - Edema – cardiac, hepatic or renal
  - Acute pulmonary edema
  - Cerebral edema
  - Hypertension
  - Hypercalcemia and renal calcium stones

Thiazides

- inhibit reabsorption by Na^+/Cl^- symporter
- **Uses**
  - Edema
  - Hypertension
  - Diabetes insipidus
  - Hypercalciuria

Carbonic anhydrase inhibitors

- inhibit H^+ secretion, resultant promotion of Na^+ and K^+ excretion
- **Uses**
  - Glaucoma
  - Epilepsy
  - Acute mountain sickness
  - Periodic paralysis

Potassium-sparing diuretics

- inhibition of Na+/K+ exchanger:
- **Uses**
  - Edema : cirrhotic and nephritic edema
  - To counteract K^+ loss due to thiazide and loop diuretics.

Osmotic diuretics

- promote osmotic diuresis
- **Uses**
  - Increased intracranial or intraocular tension.
  - To maintain g.f.r and urine flow in impending acute renal failure.

Oedema:

Definition:

The term oedema signifies increased fluid in the interstitial tissue spaces.

Anasarca is a severe and generalized oedema with profound subcutaneous tissue swelling.

Pathophysiologic categories of oedema

- Increased hydrostatic pressure
- Reduced plasma oncotic pressure
- Lymphatic obstruction
- Sodium retention
- Inflammation.

❖ Local increases in hydrostatic pressure may result from impaired venous outflow. For eg. Deep venous thrombosis in the lower extremities leads to oedema, which is restricted to the affected leg.

❖ Reduced plasma oncotic pressure can result from excessive loss or reduced synthesis of albumin, the serum protein responsible for maintaining osmotic pressure.

❖ Lymphatic obstruction: impaired lymphatic drainage and consequent lymphedema is usually localized. It results from inflammatory or neoplastic obstruction.

❖ Sodium and water retention are contributory factors in several forms of oedema;

❖ Salt retention may also be a primary cause of oedema

Table 3.4.2 Aetiology and types of oedema

Generalised oedema	Localised oedema
1. Cardiac oedema 2. Renal oedema 3. Hepatic oedema 4. Nutritional oedema 5. Cyclic- premenstrual 6. Idiopathic	1.Venous oedema 2. Lymphatic oedema 3.Inflammatory oedema 4.Allergic

Investigations

The cause of oedema is usually apparent from the history and examination of the cardiovascular system and abdomen, combined with testing the urine for protein and measuring the serum albumin level.

Liver function test

Renal function test

Complete haemogram

Serum electrolytes

Ultrasonogram of abdomen can also be done.

Hypertension

Definition

Systemic hypertension is the persistent rise of basal blood pressure above the arbitrary level of 140/90 mm of Hg recorded on 3 or more successive occasions. There may be only systolic hypertension. In such cases systolic BP becomes 140 mm of Hg or above.

Classification of Hypertension

- Essential or Idiopathic hypertension

  Here no obvious cause is found to account for high blood pressure (90%-95% of cases)

- Secondary or Symptomatic hypertension

  (5% -10% of cases)

  1. *Renal causes* (*common*): Acute nephritic syndrome, chronic nephritis, renal artery stenosis, renal embolism

  2. *Endocrine* causes: Thyrotoxicosis and myxodema, acromegaly, Cushing syndrome.

  3. *Metabolic causes*: Diabetes mellitus, chronic gout, Atherosclerosis.

  4. *Drugs*: steroids, contraceptive pills.

  5. *Congenital*: Coarctation of aorta

  6. *Psychogenic*

  7. *Neurological*: Encephalitis, Brain tumour, cerebrovascular accidents.

  8. *Blood diseases*: Polycythaemia

Essential hypertension

Aetiology

- *Genetic factor:*

Homozygos is usually seen to be severely affected than the heterozygous.

- *Sex:*

Commonly seen in males.

- *Salt intake:*

Excessive salt intake with genetic predisposition is very important.

- *Structural changes in arterioles:*

Thickening of arteriolar wall and narrowing of the lumen lead to resistance in the blood flow.

Clinical Features

1. Pulsating headache often occipital and occurs particularly in morning.
2. Easy fatigability
3. Dizziness
4. Insomnia
5. Lack of concentration
6. Loss of memory
7. Occasional palpitation
8. Breathlessness

Symptoms of associated diseases may be present.

- **Cerebral Arteriosclerosis**

May give rise to

1. Hypertensive encephalopathy
2. Cerebral and subarachnoid haemorrhage
3. TIA
4. Convulsive Seizure

- **Renal Arteriosclerosis**

May give rise to

1.Uraemia

2.Haematuria

3.Polyuria

4.Nocturia

- **CoronaryArteriosclerosis**

  May give rise to

  1. Acute left ventricular failure
  2. Angina pectoris
  3. Coronary thrombosis

Urolithiasis

Urolithiasis is the process of forming stones in the kidney, bladder, and/or ureters (urinary tract).

Types of renal stones

Renal stones can be broadly classified into radiopaque and radiolucent stones.

- The commonest radiolucent stone is uric acid stone.
- Less common radiolucent stones include xanthine and hypoxanthine stones.
- Radiopaque stones constitute the majority of renal stones. All calcium stones are radiopaque.

Etiological classification of urolithiasis

I. Hypercalcemic states
II. Uric acid lithiasis
III. Idiopathic renal lithiasis
IV. Renal tubular syndrome and enzyme abnormalities
V. Drugs
   i. Triametrene
   ii. Acyclovir
   iii. Indinavir
   iv. Sulphonamides

Secondary nephrolithiasis

1. Cystic renal diseases
2. Urinary diversion procedures
3. Stents, suture materials
4. Catheters

Clinical features

- Colicky pain often associated with macroscopic or microscopic hematuria.

- The pain due to stone in renal pelvis is often abrupt in onset, intense in severity, intermittent and radiates from groin to loin.
- The colic due to mid -ureteric stone is characterized by radiation to testes or labia.
- Bladder stone are usually associated with frequency, strangury, urgency or dysuria.
- General symptoms like sweating, nausea, and increased frequency also occur.
- Anuria may occur when the obstruction is bilateral and complete or if the urethra is totally blocked.

Table 3.4.3 Investigations of urolithiasis

Sample	Test
Stone	Chemical composition- most valuable when possible
Blood	▪ Calcium ▪ Phosphate ▪ Uric acid ▪ Urea and electrolytes ▪ Parathyroid hormone
Urine	Dip stick test for ▪ Protein ▪ Glucose ▪ Amino acids
24- hour urine	▪ Urea ▪ Creatinine clearance ▪ Sodium ▪ Calcium ▪ Oxalate ▪ Uric acid

4. MATERIALS AND METHODS

4.1. PREPARATION OF *JALAMANJARI CHENDOORAM*

பாண்டு, மகோதரம், வீக்கம், நீர்க்கட்டு இவற்றிற்கு

சலமஞ்சரி சிந்தூரம்

சலமஞ்சரி முறைகேள் சண்டைவெடி நான்குபலம்
கல்நார் மதஞ்சத்து காந்தமயம் - நல்கெந்தி
காரஞ்சீனஞ் சாரம் கற்காவி சங்குபொடி
பார்விரடை யிரண்டு பார்.

பார்பொடி யுருக்குப் பாகமதில் கட்டிவிட்டுச்
சார்பாயிஞ்சி தேன்வெல்லந் தனிற்காசு – நேரிடையாய்த்
தாக்கு இருநேரந் தங்காது பாண்டுவர்க்கம்
வீக்கமுந் தீரும் விரும்பு.

Purification methods:

- ***Ayam:***

  The iron fillings were boiled for half an hour in both sesame oil and *Piper beetle* juice respectively to get it purified.

- ***Gandhakam:***

  Sulphur is melted in a spoon with butter; it was then poured into cow's milk. The process was repeated for a total of 30 times washed in water and then dried.

- ***Gomoothira silasathu*** :

  The asphaltum was ground with cow's milk for the whole day and dried.

- ***Kaantham:***

  It was grinded with lemon juice for 45 minutes to get it purified.

- ***Kaavikkal:***

  It was soaked and grinded with tender coconut water, the mass was squeezed in a cloth and it was collected, and then dried in sun to get it purified.

- ***Kalnaar:***

  The broken pieces of Kalnaar were soaked in cow's urine for 10 days, The urine was changed daily. It was then washed with water and dried.

- ***Karpoora silasathu:***

  The impure form of silasathu is soaked in tender coconut water, boiled till it evaporates and washed to get it purified.

- ***Navacharam:***

  It was dissolved in cow's urine, filtered heated and then dried in sun and used.

- ***Padikaram:***

The lumps were dissolved in pure water, filtered and boiled in a pan, when it attains thicky molten consistency, it was allowed to cool and the crystals that crystallize out were collected.

- ***Sangu:***

To equal quantities of burnt lime stone and alkaline earth salt, 8 times of water, was added, stirred & the clear filtrate was decanted. In this solution, the conch shells were boiled from which the embedded sandy portions were removed, washed well and dried.

- ***Vediyuppu:***

The salt was dissolved in 4 times of water and boiled, at the time of boiling, the white of hen's egg was added dust separatedout and was removed. At a suitable consistency, the solution is transferred to a wide vessel, mouth of which is covered with a cloth and allowed to remain in a room where there are no wind disturbances. The crystals that were separated was again subjected to the above processes 7 more times and used.

- ***Venkaaram:***

Venkaaram is heated on a pan till it complete dehydrates

Ingredients

1. Purified Iron Filings – *Suththi Seitha Ayapodi* 70gms
2. Purified Sulphur – *Suththi Seitha Ganthakam* 70gms
3. Purified Asphaltum – *Suthi Seitha Gomoothira Silasathu* 70gms
4. Purified Magnetic oxide of iron – *Suththi Seitha Kaantham* 70gms
5. Purified Red ochre – *Suththi Seitha Kaavikkal* 70gms
6. Purified Asbestos – *Suththi Seitha Kalnaar* 70gms
7. Purified crystallised foliated Gypsum – *Suththi Seitha Karpoora Silasaththu* 70gms
8. Purified ammonium chloride – *Suthi Seitha Navacharam* 70 gms
9. Purified Alum– *Suththi Seitha Padikaram* 70gms

10. Purified conch shells – *Suththi seitha sangu* 70gms

11. Borax, Dehydrated – *Poriththa Venkaram* 70gms

12. Purified Salt Petre – *Suthi Seitha Vediyuppu* 140gms

Method of preparation

The purified drugs were powdered separately. The powders were mixed and grinded again into a very fine powder.

A shallow container was heated and some amount of the powder was sprinkled in to it. The mixture first melted and then solidified. The solid was taken and allowed to cool. Similarly all the powders were used and the solidified products obtained were grinded into a very fine powder.

Indications

- Oedema,
- Anaemia,
- Swellings,
- Ascites,
- Suppression or retention of urine.

Fig 4.1.1 *Jalamanjari chendooram*

Purified ingredients of *Jalamanjari Chendooram*

Fig 4.1.2 Purified *vediyuppu*

Fig 4.1.3 Purified *kalnaar*

Fig 4.1.4 Purified *gomoothira silasathu*

Fig 4.1.5 Purified *Karpoora Silasathu*

Fig 4.1.6 Purified *Kaantham*

Fig 4.1.7 Purified *Ayam*

Purified ingredients of *Jalamanjari Chendooram*

Fig 4.1.8 Purified *Ganthakam*

Fig 4.1.9 Purified *Venkaaram*

Fig 4.1.10 Purified *Padikaram*

Fig 4.1.11 Purified *Navachaaram*

Fig 4.1.12 Purified *Kaavikkal*

Fig 4.1.13 Purified *Sangu*

4. 2 STANDARDIZATION OF DRUG

4.2.1.1 PHYSICO-CHEMICAL ANALYSIS:

Procedures:

Total ash

Two grams of grounded air-dried material was accurately weighed in a previously ignited and tared silica crucible. The drug was gradually ignited by raising the temperature to 450°C until it was white. The sample was cooled in a desiccator and weighed. The percentage of total ash was calculated with reference to air-dried drug.

Acid Insoluble ash

The ash was boiled with 25 ml of 2 M hydrochloric acid for 5 minutes, the insoluble matter was collected on an ash less filter paper, washed with hot water, ignited, cooled in a desiccator, and weighed. The percentage of acid insoluble ash was calculated with reference to the air-dried drug.

Water Soluble ash

The ash was boiled with 25 ml of water for 5 minutes, the insoluble matter on ash less filter paper collected, washed with hot water, ignited, cooled in a desiccator, and weighed. The weight of the insoluble matter from the weight of the total ash was subtracted; the difference represents the water soluble ash. The percentage of water insoluble ash was calculated with reference to the air-dried drug.

Determination of loss on drying

. The sample was dried in an oven at 100^{o}C -105^{o}C until two consecutive weighing did not differ by more than 5 mg.

.

Potential of Hydrogen **(pH):**

The pH scale is logarithmic and runs from 0.0 to 14.0 with 7.0 being neutral. Readings less than 7.0 indicate acidic solutions, while higher readings indicate alkaline or base solutions.

4.2.1.2 FOURIER TRANSFORM INFRARED SPECTROSCOPY (FTIR)

Instrument Details:

Model	**: Spectrum one: FT-IR Spectrometer**
Scan Range	**: MIR 450-4000 cm-1**
Resolution	**: 1.0 cm-1**

Sample required : 50 mg, solid or liquid.

Fourier Transform Infrared Spectroscopy (FTIR) is an analytical technique used to identify mainly organic materials. FTIR analysis results in absorption spectra which provide information about the chemical bonds and molecular structure of a material. The FTIR spectrum is equivalent to the "fingerprint" of the material and can be compared with cataloged FTIR spectra to identify the material.

Fourier transform infrared spectroscopy analytical capabilities:

- Identifies chemical bond functional groups by the absorption of infrared radiation which excites vibrational modes in the bond
- Especially capable of identifying the chemical bonds of organic materials
- Detects and identifies organic contaminants
- Identifies water, phosphates, sulphates, nitrates, nitrites, and ammonium ions
- Detection limits vary greatly, but are sometimes $<10^{13}$ bonds/cm^3 or sometimes sub monolayer
- Useful with solids, liquids, or gases

To confirm the acid and basic radicals of the trial drug to ensure the inorganic constituents

4.2.1.3. SCANNING ELECTRON MICROSCOPE (SEM):

The Scanning Electron Microscope (SEM) is a microscope that was electrons rather than light to form an image. There are many advantages in using the SEM instead of a light microscope.

Resolution : 1.2 nm gold particle separation on a carbon substrate

Magnification : From a min of 12 X to greater than 1, 00,000 X

The SEM has a large depth of field, which allows a large amount of the sample to be in focus at one time. The SEM also produces images of high resolution, which means that closely spaced features can be examined at a high magnification. Preparation of the samples is relatively easy since most SEM one require the sample to be conductive.

The combination of higher magnification, larger depth of focus, greater resolution, and easy of sample observation marks the SEM one of the most heavily used instruments in research areas today.

4.2.2. PROXIMATE CHEMICAL ANALYSIS OF A DRUG

Methodology for chemcial analysis

Preparation of Extract:

- Add 5 gm of the *Jalamanjari chendooram* to 50ml of distilled water.
- Boil the solution for 20 minutes, cool and then filter.
- Use the Extract for the following tests.

Table 4.2.2 Methodology for chemcial analysis

S.No	Experiment	Observation	Inference
1.	**Test for reducing Sugar :** To 5ml of Benedicts qualitative reagent, add 10 drops of extract, then boil for two minutes	Absence of Green / Yellow / Red PPT	Abesence of Reducing Sugar
2.	**Test for Starch :** To 5 ml of extract add 2ml of acetic acid and then add few drops of N/50 Iodine Solution.	Absence of Blue Colour	Absence of Starch
3.	**Test for Proteins :** To 2 ml of extract, add 2ml of 5% Sodium Hydroxide mix and add 2 drops of Copper Sulphate Solution.	Absence of Violet or Purple Colour	Absence of Proteins
4.	**Test for amino Acid :** Place 2 drops of extract on a filter paper and allow to dry well. Then spray 1% ninhydrin over the same and allow to dry.	Absence of Violet Colour	Absence of Amino Acid
5.	**Test for Albumin :** To 2 ml of extract, add 2ml of Esboch's reagent.	Absence of Yellow PPT	Absence of Albumin
6.	**Test for Phosphate :** To 2ml of extract, add 2ml of ammonium Molybdate solution and 2ml of concentrated Nitric Acid.	Presence of Yellow PPT	Presence of Phosphate

S.No	Experiment	Observation	Inference
7.	**Test for Sulphate :** To 2 ml of extract add 2ml of 4% ammonium oxalate solution.	Presence of White PPT	Presence e of Sulphate
8.	**Test for Chloride :** Add 2ml of extract to dilute nitric acid till the effervescence ceases. Then add 2 ml of Silver Nitrate Solution.	Presence of Cloudy White PPT	Presence of Chloride
9.	**Test for Iron :** To 2ml of extract, add 2ml of ammonium thio cynate solution and add 2ml of concentrated Nitric Acid.	Presence of Red Colour	Presence of Iron
10.	**Test for Calcium :** To 2 ml of extract, add 2 ml of 4% ammonium Oxalate Solution.	Absence of White PPT	Absence of Calcium
11.	**Test for Sodium :** Make a paste with 2 pinches of the sample with Hcl and Introduce it into the blue flame.	Absence of Yellow Flame	Absence of Sodium
12.	**Test for Potassium :** Add a pinch of the sample to 2 ml of Sodium Nitrate Solution. Then add 2ml of Cobal Nitrate in 20% acetic acid.	Absence of Yellow PPT	Absence of Potassium
13.	**Test for Zinc :** To 2ml of extract, add few drops of Sodium Hydroxide.	Absence of White PPT	Absence of Zinc
14.	**Test for Magnesium :** To 2ml of extract, add few drops of Sodium Hydroxide Solution	Absence of White PPT	Absence of Magnesium

S.No	Experiment	Observation	Inference
15.	**Test for Alkaloids :** a. To 2ml of extract, add 2ml of Potassium Iodide Solution b. To 2ml of extract add 2ml of Picric Acid. c. To 2 ml of extract add 2ml of Phosphotungstic Acid.	Absence of Red Colour Absence of Yellow Colour Absence of White PPT	Absence of Alkaloids Absence of Alkaloids Absence of Alkaloids
16.	**Test for Tannic Acid :** To 2ml of extract add 2 ml of Ferric Chloride Solution	Absence of Black PPT	Absence of Tannic Acid

4. 3. TOXICITY STUDY OF JALAMANJARI CHENDOORAM

4.3.1. PROCEDURE OF ACUTE TOXICITY STUDY:

Animals:

Mice of either sex weighing 25-30g and rats weighing 210-240g were obtained from the animal house of Vels University. The animals were used with the approval of the Institute animal ethics committee and obtained from Vels University, Chennai. They were fed with a balanced standard pellet diet and maintained under standard laboratory conditions, providing 24-28^{0}C temperature, standard light cycle (12 h light, 12 h dark) and water ad libitum. Animals were kept in cages with raised floors of wide mesh to prevent coprophagy. Animal welfare guidelines were observed during the maintenance period and experimentation. The rats were randomly assigned to control and different treatment groups, six animals per group. The animals were acclimatized for one week under laboratory conditions.

Acute Toxicity Study-OECD 425 Guidelines

Acute oral toxicity test for the *Jalamanjari Chendooram* was carried out as per OECD Guidelines 425. As with other sequential test designs, care was taken to ensure that animals are available in the appropriate size and age range for the entire study. The test substance is administered in a single dose by gavage using a stomach tube or a suitable intubation cannula. The fasted body weight of each animal is determined and the dose is calculated according to the body weight. After the substance has been administered, food was withheld for a further 2 hours in mice. The animals were observed continuously for the first 4 h and then each hour for the next 24 h and at 6 hourly intervals for the following 48 h after administering of the test drug, to observe any death or changes in general behaviour and other physiological activities. Single animals are dosed in sequence usually at 48 h intervals. However, the time interval between dosing is determined by the onset, duration, and severity of toxic signs. Treatment of an animal at the next dose was delayed until one is confident of survival of the previously dosed animal.

Observation of toxicity signs*:* General behavior, respiratory pattern, cardiovascular signs, motor activities, reflexes, change in skin and fur, mortality and the body weight changes were monitored daily. The time of onset, intensity, and duration of these signs, if any, was recorded

4.3.2 SUB-ACUTE TOXICITY

In a 28-days sub acute toxicity study, twenty four either sex (3+3) rats were divided into four groups of 6 rats each. Group I that served as normal control was administered with distilled water (p.o.) while groups II, III and IV were administered daily with the *Jalamanjari Chendooram* (p.o.) for 28 days at a dose of 25, 50 and 100mg/kg respectively. The animals were then observed daily for gross behavioural changes and any other signs of subacute toxicity. The weight of each rat was recorded on day 0 and weekly throughout the course of the study, food and water consumption per rat was calculated. At the end of the 28 days they were fasted overnight, each animal was anaesthetized with diethylether, following which they were then dissected and blood samples were obtained by cardiac puncture into heparinised tubes. The blood sample collected from each rat was centrifuged with 3000 X g at 4^{o}C for 10 min to separate the serum and used for the biochemical assays.

Hematological and blood biochemical analyses:

At the end of the study, all animals were kept fasted for 16-18 h and then anesthetized with anesthetic ether on the 28th day. Blood samples for hematological and blood chemical analyses were taken from retro orbital vein. Heparinized blood samples were taken for determining complete blood count (white blood cell count, differential white blood cell count, platelet count, red blood cell count, hematocrit, and hemoglobin) by semiautomated hematology analyzer. The serum from non-heparinized blood was carefully collected for blood chemistry and enzyme analysis, glucose, creatinine, total protein, albumin, total and direct bilirubins, serum glutamate-oxaloacetate transaminase (SGOT), serum glutamate pyruvate transaminase (SGPT), and alkaline phosphatase (ALP)) were automatically determined using autoanalyzer.

Necropsy:

All rats were sacrificed after the blood collection. The positions, shapes, sizes and colors of internal organs were evaluated. The Spleen, Testes, Pancreas, Lung, Liver, Brain, Heart, Stomach, Intestine, Bone, Ovary, and Kidney tissues were excised from all rats to visually detect gross lesions, and weighed to determine relative organs' weights and preserved in 10% neutral formalin for histopathological assessment. The tissues were embedded in paraffin, and then sectioned, stained with haematoxylin and eosin and were examined microscopically.

Statistical analysis

Values were represented as mean ± SEM. Data were analysed using one-way analysis of variance (ANOVA) and group means were compared using the Tukey-Kramer Multiple Comparison Test using GraphPad Instat-V3 software. P values < 0.05 were considered significant.

4.4. DIURETIC ACTIVITY OF *JALAMANJARI CHENDOORAM* IN RATS

Evaluation of Diuretic activity:

The screening was performed on healthy rats. Frusemide (20 mg/kg) was used as reference standard and *Jalamanjari Chendooram* were dissolved in saline solution for administration while normal saline (25 ml/kg) was used as vehicle. The rats were divided in 4 groups each containing 6 rats (n = 6). Rats were kept for fasting for 18 hrs before the study.

The control group received normal saline and test groups received 25 and 50mg/kg of *Jalamanjari Chendooram* dissolved in normal saline. The doses of *Jalamanjari Chendooram* were decided on the basis of acute toxicity study. The doses were given by oral route and rats were kept in specially designed metabolic cages for the collection of urine for 6 hrs. The urine volume during 6 hrs is measured and urine electrolyte estimation was carried out for Na+, K+ using flame photometer and Cl- was estimated by titration.

Fig.4.4 Evaluation of Diuretic activity of *Jalamanjari Chendooram*

4.5. CLINICAL STUDY OF *JALAMANJARI CHENDOORAM*

Objectives

- To evaluate the Diuretic activity of *Jalamanjari chendooram.*
- To explore the efficacy of in patients with Oedema, Hypertension, Urolithiasis.

Design of the study

Open clinical trial phase II B

Study centre

Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Arumbakkam, Chennai –106.

Study participants

Both men and women and members of all races and ethnic groups are eligible for this trial. Treatment will be administered on an *inpatient/outpatient* basis. The patients will be selected from the In-patient and Out-patient department of Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Chennai – 106.

Number of subjects

Number of participants were 50.

Registration process

To register a patient, the following documents were completed by the investigator.

- Copy of required laboratory tests
- Signed patient consent form
- *Other appropriate forms (e.g., Eligibility Screening Worksheet, Registration Form).*

The investigator will then verify eligibility and will assign a patient study number, drug dose and register the patient on the study.

Criteria for inclusion

Patients with Oedema, Hypertension, Urolithiasis are eligible for entry to the trial if the following criteria are satisfied.

The criteria of inclusion are:

- Oedema of lower extremity
- Raised systolic and diastolic blood pressure ≥140/90.
- Pain present in the either/both loins.
- Patients with known urolithiasis with USG reports.

- ❖ Co operative patients
- ❖ The previous drug regimen if any have been with held for 24 hours before the clinical trial.

Criteria for exclusion

- ❖ Severly ill patients.
- ❖ AIDS
- ❖ Malignancy
- ❖ Pregnant and lactating women
- ❖ TB
- ❖ Cardio vascular disorder
- ❖ Age below 10 years
- ❖ Syphilis

Withdrawal Criteria

Patients were removed from study when any of the criteria listed below applies. The reason for study removal and the date the patient will be removed must be documented in the Case Report Form.

In the absence of treatment delays due to adverse events, treatment may continue for 2 cycles or until one of the following criteria applies:

- ❖ Disease progression,
- ❖ Deterioration of vital signs with cardiac, respiratory, hepatic, renal and CNS changes.
- ❖ Intercurrent illness that prevents further administration of treatment,
- ❖ Unacceptable adverse event(s),
- ❖ Patient decides to withdraw from the study, or
- ❖ General or specific changes in the patient's condition render the patient unacceptable for further treatment in the judgment of the investigator.

Routine examination and assessment

The full details of history and physical examination of the patients is to be recorded as per the proforma. The clinical assessment will be done initially at the end of every week during treatment and at the end of the follow up. The laboratory investigation and the physiological parameters will be recorded initially at the end of the treatment and at the end of follow up as per the proforma. 24hrs urine volume estimation will be done in all patients before and after the intake of the drug

Trial drug

Jalamanjari Chendooram

Dosage

Dose will be fixed after finding the LD50.

Duration of trial

Study Period: 7weeks with 2 months follow up.

Total duration: 2 months

Treatment plan

Administration of the drug:

Form of the medicine	: *Chendooram*
Route of Administration	: Enteral
Dose	: 200mg
Times of Administration	: Two times a day; after food
Duration	: 3-7 weeks

Diet restriction and medical advice:

- The patients will be instructed to follow easily digestible foods.
- They will be advised to take tender coconut, and vegetables like radish, juice of plantain stem. Avoid bitter gourd, agathi greens, brinjal, and non-vegetarian diet.
- The patient will advise to avoid cold damp climate.
- The patient will be advised to take rest.
- The clinical improvement will be observed and recorded daily in the proforma of case sheet.

Trial conduct

This study was conducted in compliance with the protocol approved by the Institutional Review Board, and according to Good Clinical Practice standards. No deviation from the protocol was implemented without the prior review and approval of the IRB except where it may be necessary to eliminate an immediate hazard to a research subject. In such case, the deviation was reported to the IRB

Classification of results

1. **Good Response**

   Relief of Symptoms above 75% and improvement towards normalcy in laboratory parameters.

2. **Fair Response**

   50% to 75% relief in symptoms. Significant improvement in laboratory parameters.

3. **Poor Response**

   25% to 49% relief in symptoms and minimal improvement in laboratory parameters.

4. **No Response**

   No relief in symptoms and no significant improvement in laboratory parameters.

Follow up

Assessment was taken for every three days before treatment and after treatment. During this period clinical assessment and laboratory investigation was carried out.

Statistical Analysis

The data were tabulated and analyzed by students 'T' test.

Ethical review

This protocol and any amendments were submitted to the Govt siddha medical college Institutional Ethical Committee (IEC) for formal approval to conduct the study. The decision of the IEC concerning the conduct of the study was made in writing to the investigator.

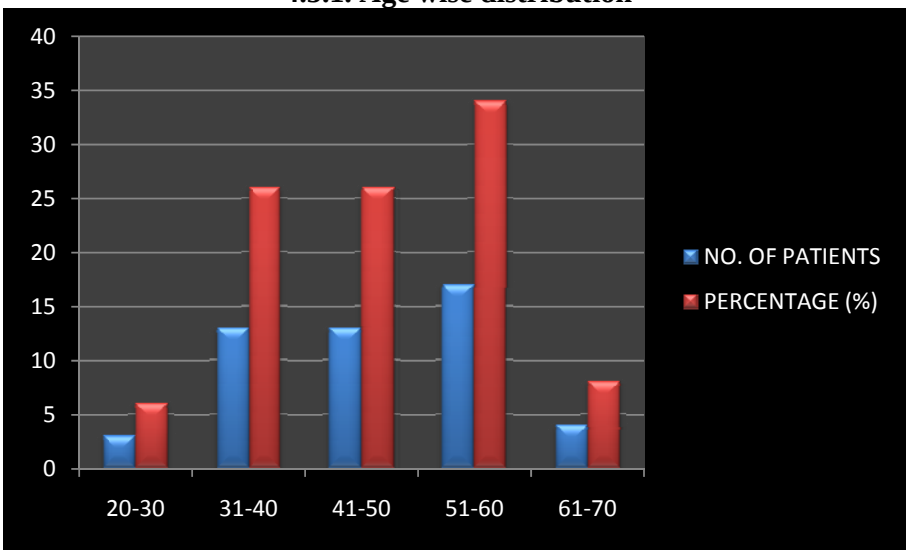
All subjects for this study were provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form was submitted with the protocol for review and approval by the IEC. The formal consent of a subject, using the IEC-approved consent form, was obtained before that subject is submitted to any study procedure. This consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

4.5. CLINICAL ASSESSMENT

Table 4.5.1 Age wise distribution

SL. NO	AGE IN YEARS	NO. OF PATIENTS	PERCENTAGE (%)
1	20-30	3	6
2	31-40	13	26
3	41-50	13	26
4	51-60	17	34
5	61-70	4	8
TOTAL		50	100

4.5.1. Age wise distribution



Inference:

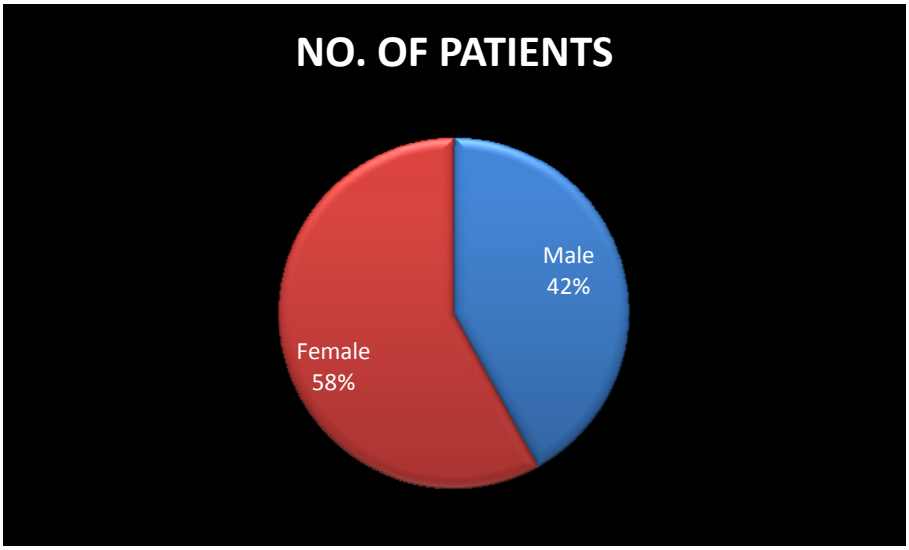
Among 50 patients,

- 3 patients belongs to the age group of 20-30 years
- 13 patients belongs to the age group of 31-40 years
- 13 patients belongs to the age group of 41-50 years
- 17 patients belongs to the age group of 51-60 years
- 4 patients belongs to the age group of 61-70 years

Table. 4.5.2. Sex distribution

Sl. No	Sex	No. of patients	Percentage
1	Male	21	42
2	Female	29	58
Total		50	100

Sex distribution



Inference:

Among 50 patients,

- 21 patients were male
- 29 patients were female

4.5.3 Clinical study on *Jala manjari chendooram* in in and out patients dept. for diuretic activity

Sl.No.	I.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
1.	1085	GOVINDARAJ	43/M	23.7.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	3.8.2012	GOOD
2.	1174	SHANTHI	52/F	1.8.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	18.9.2012	FAIR
3.	1288	DEVAKI	57/F	16.8.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	30.8.2012	GOOD
4.	1383	SAMUNDEE SWARI	56/F	30.8.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	1.10.2012	FAIR
5.	1430	KOLANJI	51/M	4.9.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	15.9.2012	GOOD
6.	62	JEYARAMAN	60/M	24.9.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	3.11.2012	GOOD
7.	77	POONGOTHAI	52/F	24.9.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	13.10.2012	GOOD
8.	457	BEEVI	65 /F	20.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	14.12.2012	GOOD
9.	483	NAGAVALLI	50/F	21.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	13.12.2012	GOOD
10.	629	KAMALA	47/F	13.12.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	24.12.2012	FAIR

4.5.4 Clinical study on *Jala manjari chendooram* in in and out patients dept. for diuretic activity

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
11.	3020	GEETHA	32/F	6.7.2012	Pain present in the loin radiating to groin,dizziness and tiredness present	22.9.2012	GOOD
12.	1652	SEETHA	34/F	22.9.2012	Pain present in the rt loin ,nausea,dizziness ,tiredness present	05.11.2012	FAIR
13.	3425	SAJISH	29/M	29.9.2012	Pain present in the loin radiating to groin, hematuria, nausea, tiredness present	25.10.2012	GOOD
14.	4359	VIJAYA	50/F	3.10.2012	Swelling& pitting present in lower extremity,tiredness, present	05.11.2012	GOOD
15.	5043	HARISH	59/M	11.10.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	11.12.2012	GOOD
16.	7034	MANIVASAKAM	50/M	14.10.2012	Swelling pitting oedema present in lower extremity,tiredness	21.12.2012	GOOD
15.	7050	SATHEESH	39/M	14.10.2012	Pain present in the rt loin ,nausea,dizziness ,tiredness present	11.12.2012	GOOD
16.	7966	MANIKKAM	60/M	18.10.2012	Swelling pitting oedema present in lower extremity,tiredness	11.11.2012	GOOD
19.	7979	JEYA	29/F	18.10.2012	Swelling, pitting oedema present in lower extremity,tiredness	18.12.2012	FAIR
20.	8191	MISHBAH	62/F	19.10.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	24.11.2012	GOOD

1.5.5 Clinical study on *Jala manjari chendooram* in in and out patients dept. for diuretic activity

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
21.	8199	GAYATHRI	32/F	19.10.2012	Pain present in the loin radiating to groin, dizziness and tiredness present	22.12.2012	GOOD
22.	8252	FARITHA	34/F	20.10.2012	Pain present in the rt loin ,nausea, dizziness ,tiredness present	05.12.2012	FAIR
23.	8325	MAHESH	29/M	20.10.2012	Pain present in the loin radiating to groin, hematuria, nausea, tiredness present	25.12.2012	GOOD
24.	8359	KAVYA	33/F	20.10.2012	Swelling & pitting present in lower extremity,tiredness, present	05.11.2012	GOOD
25.	8601	BOOBESH	39/M	21.10.2012	Pain present in the rt loin ,nausea, dizziness ,tiredness present	11.12.2012	GOOD
26.	8656	VIVEKAN	34/M	21.10.2012	Swelling pitting oedema present in lower extremity, tiredness	28.11.2012	GOOD
27.	8706	REBECCA	41/F	22.10.2012	Swelling, pitting oedema present in lower extremity, tiredness	30.12.2012	GOOD
28.	8711	PREMA	50/F	22.10.2012	Swelling, pitting oedema present in lower extremity, tiredness	19.11.2012	FAIR
29.	9999	JEYAMALA	39/F	29.10.2012	Swelling, pitting oedema present in lower extremity, tiredness	18.12.2012	GOOD
30.	942	SENTHILKUMAR	55/M	3.11.2012	Diziness, headache, loss of sleep, tiredness, difficulty in breathing	12.12.2012	FAIR

4.5.6. Clinical study on *Jala manjari chendooram* in in and out patients dept. for diuretic activity

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
31.	1383	ANDAL	55/F	5.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	16.12.2012	FAIR
32.	1382	MAHESHWARI	60/F	5.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	20.12.2012	FAIR
33.	1683	SURYA	55/M	6.11..2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	20.12.2012	GOOD
34.	1681	JEYARAM	45/M	6.11..2012	Pain present in the rt loin ,nausea,dizziness ,tiredness present	19.12.2012	GOOD
35.	1938	SASIKUMAR	45/M	7.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in Breathing	31.12.2012	FAIR
36.	1939	KAMATCHI	61/F	7.11.2012	Swelling pitting of the oedema present in lower extremity,tiredness	19.12.2012	GOOD
37.	1940	MUTHURAMAN	52/M	7.11.2012	Swelling pitting of the oedema present in lower Extremity,tiredness	21.12.2012	GOOD
38.	1941	RAMANI	45/F	7.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	19.12.2012	GOOD
39.	3682	JAARUBA	40/F	17.11.2012	Swelling pitting of the oedema present in lower Extremity,tiredness	18.12.2012	FAIR
40.	5405	BIJALI	32/F	24.11.2012	Pain present in the rt loin ,nausea,dizziness ,tiredness present	31.12.2012	GOOD

4.5.7 Clinical study on *Jala manjari chendooram* in in and out patients dept. for diuretic activity

Sl.No.	O.P. No.	Name	Age/ Sex	Date of first visit	Symptoms	Date of last visit	Results
41.	5483	DANAM	55/F	24.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	16.12.2012	GOOD
42.	5553	MAHESHWARI	60/F	25.11.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	28.12.2012	FAIR
43.	5583	SURYA	55/M	26.11..2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	20.12.2012	GOOD
44.	5681	JEYARAM	45/M	28.11..2012	Pain present in the rt loin ,nausea,dizziness ,tiredness present	19.12.2012	GOOD
45.	5938	KUMAR	45/M	5.12.2012	Diziness, headache,loss of sleep,tiredness,difficulty in Breathing	31.12.2012	FAIR
46.	5939	KAMALINI	61/F	5.12.2012	Swelling pitting of the oedema present in lower extremity,tiredness	29.12.2012	GOOD
47.	6940	MUTHU	52/M	7.12.2012	Swelling pitting of the oedema present in lower Extremity,tiredness	31.12.2012	GOOD
48.	6941	RAMADEVI	45/F	7.12.2012	Diziness, headache,loss of sleep,tiredness,difficulty in breathing	29.12.2012	GOOD
49.	7432	RUBY	40/F	08.12.2012	Swelling pitting of the oedema present in lower Extremity,tiredness	28.12.2012	GOOD
50.	7461	GOPI	32/M	08.12.2012	Pain present in the rt loin ,nausea, ,tiredness present	31.12.2012	FAIR

4.5.8.1. General Haematological Investigation

Sl. No.	I.P. No.	Name	Age/ Sex	HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)		Hb(Gm)		BL.UREA		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT AT		BT	AT	BT	AT	AL B	SU G	DEP	AL B	SUG	DEP
					P	L	E		P	L	E	1 hr	1hr										
1.	1085	GOVINDARAJ	48/M	8500	64	32	4	8600	51	44	5	12	11	9.0	9.3	27	28	NIL	NIL	NIL	NIL	NIL	NIL
2.	1174	SHANTHI	63/M	8800	62	33	5	9900	60	34	3	12	12	10	12.3	29	30	NIL	NIL	NIL	NIL	NIL	NIL
3.	1288	DEVAKI	50/M	6100	64	31	5	6300	51	44	5	10	14	11.0	11.6	35	37	NIL	NIL	NIL	NIL	NIL	NIL
4.	1383	SAMUNDEE SWARI	55/M	9800	57	38	5	9800	58	38	4	11	12	13.0	13.6	32	31	NIL	NIL	NIL	NIL	NIL	NIL
5.	1430	KOLANJI	53/M	8300	52	41	7	9200	62	26	8	14	15	11.0	12.4	23	21	NIL	NIL	NIL	NIL	NIL	NIL
6.	62	JEYARAMAN	50/M	7600	63	34	3	8000	52	44	4	16	15	12.0	13.4	30	26	NIL	NIL	NIL	NIL	NIL	NIL
7.	77	POONGOTHAI	62/M	9400	57	36	7	10100	63	33	4	15	14	11.0	12.7	23	22	NIL	NIL	NIL	NIL	NIL	NIL
8.	457	BEEVI	52 /M	8700	59	35	6	8800	58	39	3	12	13	11.0	12.7	35	33	NIL	NIL	NIL	NIL	NIL	NIL
9.	483	NAGAVALLI	55/M	10400	63	31	6	9400	62	33	5	13	14	10.0	13.4	31	35	NIL	NIL	NIL	NIL	NIL	NIL
10.	629	KAMALA	55/M	7600	48	46	6	7800	55	40	5	11	12	12.0	14.0	25	24	NIL	NIL	NIL	NIL	NIL	NIL

4.5.8.2. General Haematological Investigation

Sl. No.	O.P. No.	Name	Age/ Sex	4.5.8.2 HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				BL.UREA		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT 1 hr	AT 1hr	Hb(Gm)		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E			BT	AT								
11.	3020	GEETHA	32/F	7900	55	39	06	9500	57	39	4	30	14	9.0	9.3	23	22	NIL	NIL	OEC	NIL	NIL	NIL
12.	1652	SEETHA	34/F	7600	48	46	6	7800	52	43	5	14	13	10.2	10.1	34	33	NIL	NIL	NIL	NIL	NIL	NIL
13.	3425	SAJISH	29/M	9700	59	36	5	9430	65	30	5	13	24	10.6	10.6	33	35	NIL	NIL	OPC	NIL	NIL	NIL
14.	4359	VIJAYA	50/F	9700	63	29	8	9200	53	42	5	33	13	10.6	11.8	25	24	NIL	NIL	NIL	NIL	NIL	NIL
15.	5043	HARISH	59/M	7600	63	32	5	8000	51	45	4	16	15	12.0	13.4	30	26	NIL	NIL	OPC	NIL	NIL	NIL
16.	7034	MANIVASAKAM	50/M	9400	56	36	8	9100	60	36	4	17	14	11.0	12.8	23	22	NIL	NIL	OPC	NIL	NIL	NIL
17.	7050	SATHEESH	39/M	8700	57	37	6	9800	60	56	4	14	13	13.0	13.7	34	33	NIL	NIL	NIL	NIL	NIL	NIL
18.	7966	MANIKKAM	60/M	9800	63	31	6	9400	62	33	5	14	14	8.6	10.4	33	35	NIL	NIL	NIL	NIL	NIL	NIL
19.	7979	JEYA	29/F	9800	64	30	6	8500	52	44	4	12	11	9.0	9.8	29	30	NIL	NIL	NIL	NIL	NIL	NIL
20.	8191	MISHBAH	62/F	8600	62	33	5	9900	62	33	5	12	12	12.0	12.3	30	28	NIL	NIL	NIL	NIL	NIL	NIL
21.	8199	GAYATHRI	32/F	7100	64	31	5	8500	61	34	5	12	14	11.0	11.6	23	22	NIL	NIL	NIL	NIL	NIL	NIL
22.	8252	FARITHA	34/F	9800	59	36	5	9800	59	37	4	11	12	13.0	13.6	34	33	NIL	NIL	NIL	NIL	NIL	NIL
23.	8325	MAHESH	29/M	9200	52	39	9	9200	58	38	4	16	15	10.0	11.4	29	30	NIL	NIL	NIL	NIL	NIL	NIL
24.	8359	KAVYA	33/F	7800	57	38	5	7900	54	42	4	15	14	9.0	9.3	30	28	NIL	NIL	NIL	NIL	NIL	NIL
25.	8601	BOOBESH	39/M	9800	55	37	8	9800	55	43	1	13	12	10.2	10.1	23	22	NIL	NIL	NIL	NIL	NIL	NIL
26.	8656	VIVEKAN	34/M	9700	60	36	4	9800	58	37	5	14	13	10.6	10.0	34	33	NIL	NIL	NIL	NIL	NIL	NIL
27.	8706	REBECCA	41/F	8600	55	39	6	8700	56	38	6	15	14	10.8	13.1	29	30	NIL	NIL	OPC	NIL	NIL	NIL
28.	8711	PREMA	50/F	7200	55	39	6	8000	57	37	6	14	15	11.0	10.1	35	37	NIL	NIL	OPC	NIL	NIL	NIL
29.	9999	JEYAMALA	39/F	8400	61	36	3	9300	62	35	3	11	13	9.0	9.9	28	29	NIL	NIL	NIL	NIL	NIL	NIL
30.	942	SENTHILKUMAR	55/M	8700	5	35	6	8800	58	56	6	14	13	13.0	13.7	33	33	NIL	NIL	OPC	NIL	NIL	NIL

g4.5.8.3. General Haematological Investigation

Sl. No.	O.P. No.	Name	Age/ Sex	4.5.8.3 HAEMATOLOGICAL REPORT														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR (mm)				BL.UREA		BT			AT		
				TC CU/mm	DC			TC CU/mm	DC			BT	AT	Hb(Gm)		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P	L	E		P	L	E	1 hr	1hr	BT	AT								
31.	1383	ANDAL	55/F	9300	55	32	13	9500	55	35	10	15	14	9.0	9.6	23	22	NIL	NIL	NIL	NIL	NIL	NIL
32.	1382	MAHESHWARI	60/F	7600	48	46	6	7800	51	44	5	14	13	10.2	121	34	33	NIL	NIL	NIL	NIL	NIL	NIL
33.	1683	SURYA	55/M	8600	59	34	7	9430	65	32	3	13	24	10.6	10.6	33	35	NIL	NIL	OPC	NIL	NIL	NIL
34.	1681	JEYARAM	45/M	9200	53	40	7	9200	53	42	5	14	12	11.8	13.8	25	24	NIL	NIL	NIL	NIL	NIL	NIL
35.	1938	SASIKUMAR	45/M	7600	63	32	5	8000	52	44	4	13	15	12.0	13.4	30	28	NIL	NIL	OPC	NIL	NIL	NIL
36.	1939	KAMATCHI	61/F	9400	57	36	7	9100	60	36	4	15	14	12.0	12.7	23	22	NIL	NIL	OPC	NIL	NIL	NIL
37.	1940	MUTHURAMAN	52/M	8600	59	35	6	8900	60	54	6	14	13	13.0	13.7	34	33	NIL	NIL	NIL	NIL	NIL	NIL
38.	1941	RAMANI	45/F	9800	63	31	6	9400	62	33	5	12	14	10.0	124	33	35	NIL	NIL	NIL	NIL	NIL	NIL
39.	3682	JAARUBA	40/F	7800	64	32	4	8500	52	44	4	12	11	9.0	9.3	29	30	NIL	NIL	NIL	NIL	NIL	NIL
40.	5405	BIJALI	32/F	9600	62	31	7	9900	64	32	5	12	12	11.0	12.3	30	28	NIL	NIL	NIL	NIL	NIL	NIL
41.	5483	DANAM	55/F	6100	64	31	5	6300	51	44	5	12	12	11.0	11.6	23	22	NIL	NIL	NIL	NIL	NIL	NIL
42.	5553	MAHESHWARI	60/F	8800	61	34	5	9800	65	31	4	11	12	13.0	13.6	34	33	NIL	NIL	NIL	NIL	NIL	NIL
43.	5583	SURYA	55/M	9200	52	39	9	9200	58	38	4	16	15	9.0	11.4	29	30	NIL	NIL	NIL	NIL	NIL	NIL
44.	5681	JEYARAM	45/M	7800	55	38	7	7900	51	45	4	15	14	9.0	9.3	30	28	NIL	NIL	NIL	NIL	NIL	NIL
45.	5938	KUMAR	45/M	9800	55	39	6	9900	55	41	4	13	12	10.2	10.1	23	22	NIL	NIL	NIL	NIL	NIL	NIL
46.	5939	KAMALINI	61/F	7600	60	36	4	9800	60	35	5	14	13	10.6	10.0	34	33	NIL	NIL	NIL	NIL	NIL	NIL
47.	6940	MUTHU	52/M	7700	55	39	6	8700	62	34	4	15	14	10.4	13.1	29	30	NIL	NIL	OPC	NIL	NIL	NIL
48.	6941	RAMADEVI	45/F	8000	55	39	6	8000	57	37	6	14	15	9.0	10.8	35	37	NIL	NIL	OPC	NIL	NIL	NIL
49.	7432	RUBY	40/F	9200	61	36	3	9300	62	35	3	15	13	9.2	12.6	28	29	NIL	NIL	NIL	NIL	NIL	NIL
50.	7461	GOPI	32/M	8500	59	35	6	8800	59	37	4	14	13	11.0	13.7	34	33	NIL	NIL	OPC	NIL	NIL	NIL

4.5.9. 24 Hrs Urine Volume before and after administration of

Jalamanjari Chendooram

S.no	OP/IP.No	Name	Age/ Sex	24 hrs urine volume	
				Before treatment	After Treatment
1.	5852	Kumar	45/M	950ML	1300ML
2.	5807	Valliammal	55/F	1100ML	1960ML
3.	8053	Ramadas	60/M	1400ML	2100ML
4.	851	Misbara	57/F	1300ML	2500ML
5.	2698	Malliga	60/F	1600ML	2850ML
6.	2764	Manikkam	60/M	1100ML	1650ML
7.	3228	Revathi	45/F	1000ML	1950ML
8.	4000	Jayashree	35/F	1500ML	2100ML
9.	4443	Vijayalakshmi	45/F	1000ML	2030ML
10.	6290	Banumathi	59/F	1100ML	1930ML
11.	7545	Anandan	53/M	950ML	2000ML
12.	7590	Mohammed ehiya	61/M	1100ML	1600ML
13.	7656	Subramanium	68/M	980ML	1800ML
14.	8738	Shanthi	48/F	1250ML	1860ML
15.	8830	Srinivasan	45/M	1350ML	1830ML
16.	8856	Saghadev1	43/F	1540ML	2100ML
17.	9197	Ragothaman	62/M	1450ML	1830ML
18.	125	Shanthi	48/F	1340ML	1800ML
19.	515	Vijayalakshmi	45/F	950ML	1400ML
20.	528	Kanchana	60/F	945ML	1300ML
21.	8199	Gayathri	32/F	1050ML	1500ML
22.	8252	Faritha	34/F	1120ML	2395ML
23.	8325	Mahesh	29/M	1300ML	2200ML
24.	8359	Kavya	33/F	950ML	1950ML
25.	8601	Boobesh	39/M	1100ML	2250ML

4.5.9. 24 Hrs Urine Volume before and after administration of

Jalamanjari Chendooram

S.no	OP/IP.No	Name	Age/ Sex	24 hrs urine volume	
				Before treatment	After Treatment
26.	8656	Vivekan	34/M	900ML	1950ML
27.	8706	Rebecca	41/F	1050ML	1700ML
28.	8711	Prema	50/F	1400ML	2100ML
29.	9999	Jeyamala	39/F	1250ML	2000ML
30	942	Senthilkumar	55/M	2000ML	2980ML
31.	1383	Andal	55/F	1200ML	1850ML
32	1382	Maheshwari	60/F	850ML	1950ML
33.	1683	Surya	55/M	1400 ML	1800 ML
34.	1681	Jeyaram	45/M	950ML	1780ML
35.	1938	Sasikumar	45/M	1630ML	2100ML
36.	1939	Kamatchi	61/F	900ML	2100ML
37.	1940	Muthuraman	52/M	1260ML	1750ML
38.	1941	Ramani	45/F	1150ML	1600ML
39.	3682	Jaaruba	40/F	1250ML	2100ML
40.	5405	Bijali	32/F	950ML	1700ML
41.	5483	Danam	55/F	1100 ML	1760 ML
42.	5553	Maheshwari	60/F	1350 ML	1950 ML
43.	5583	Surya	55/M	1400 ML	2100 ML
44.	5681	Jeyaram	45/M	900 ML	1850 ML
45.	5938	Kumar	45/M	1250 ML	2200 ML
46.	5939	Kamalini	61/F	950 ML	1500 ML
47.	6940	Muthu	52/M	1000 ML	2000 ML
48.	6941	Ramadevi	45/F	1450 ML	2350 ML
49.	7432	Ruby	40/F	1150 ML	2400 ML
50.	7461	Gopi	32/M	1000 ML	1500 ML

5. RESULTS AND DISCUSSION

4.2.2.1 PHYSICO-CHEMICAL ANALYSIS:

S.No	Parameter	Mean Value
1.	Loss on Drying at 105°C	6.6 %
2.	Total Ash	81.55 %
3.	Acid insoluble Ash	14.9 %
4.	Particle size	Completely passes through sieve no.44
5.	pH	8.5

4.2.2.2. FTIR Results:

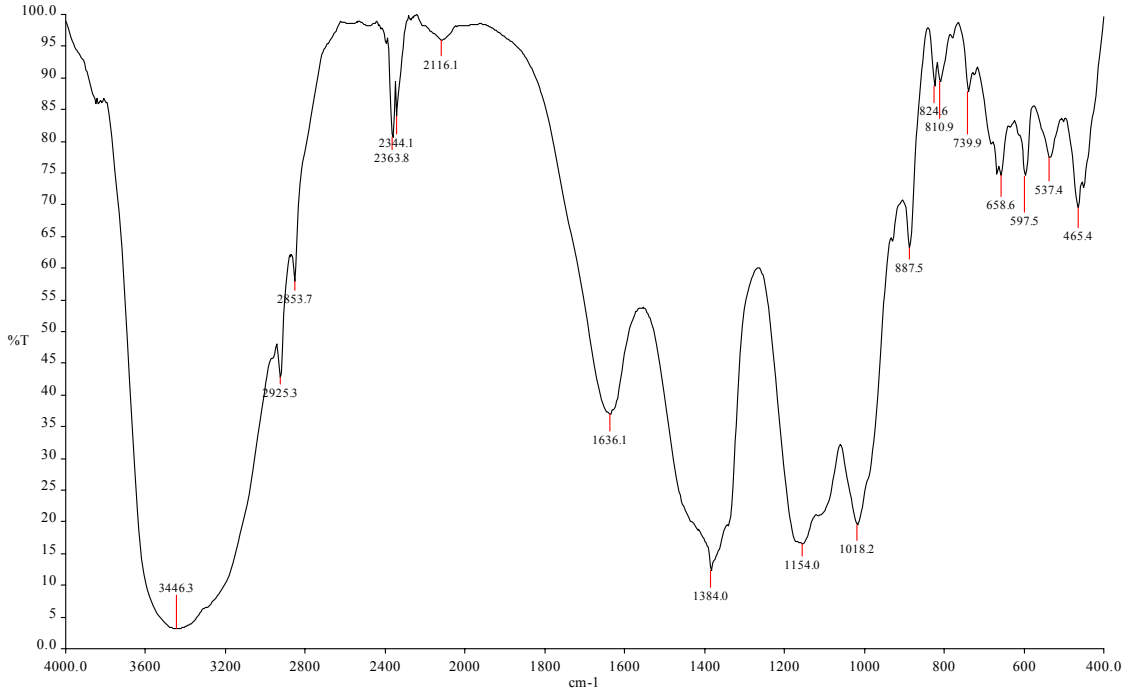


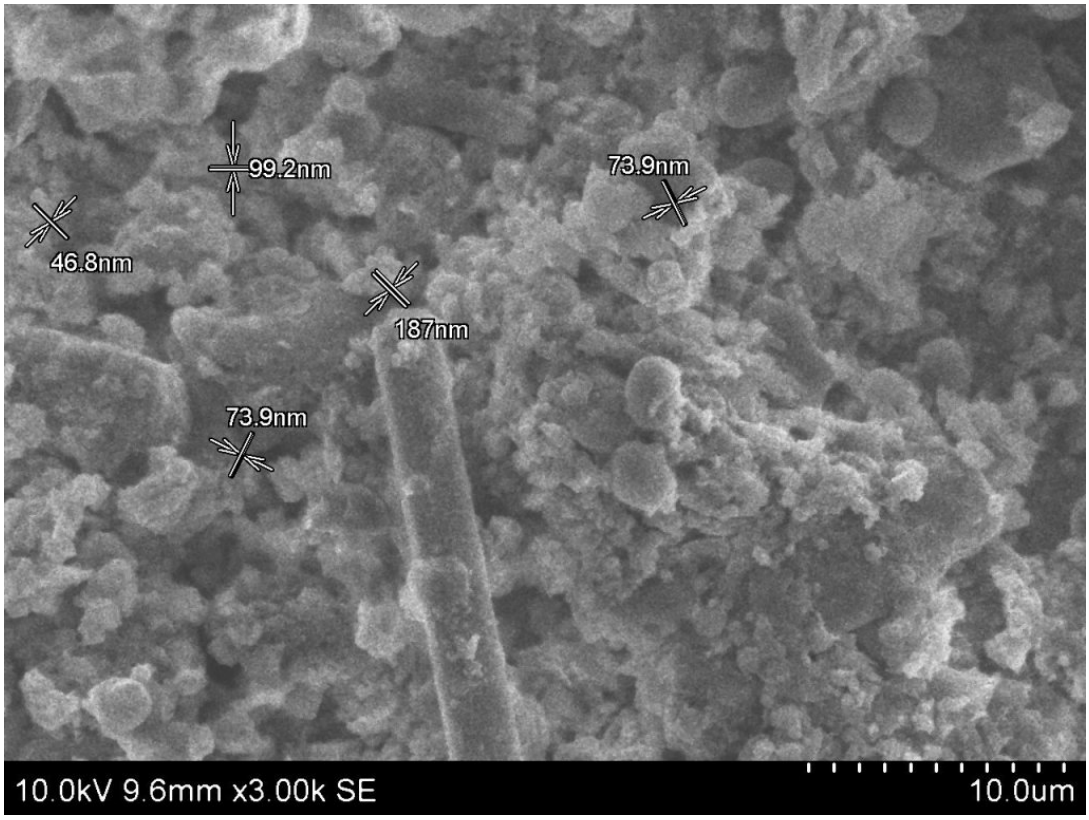
Fig.4.2.2.2. FTIR Graph

Table 4.2.2.2 FTIR results

Frequency bands	Functional Group
3446.3	Alcohol/Phenol O-H Stretch
2925.3	Carboxylic Acid O-H Stretch
2853.7	Carboxylic Acid O-H Stretch
2363.8	Phosphonates
2344.1	Phosphonates
2116.1	Alkynyl C≡C Stretch
1636.1	Aromatic C=C Bending
1384.0	Alkyl –methyl
1154.0	Alcohols – tertiary
1018.2	Fluoro alkanes – ordinary
887.5	Aromatic- meta disubstituted benzene C─H
824.6	Aromatic-para disub. benzene C─H
810.9	Aromatic-para disub. Benzene C─H
739.9	Chloroalkanes C-X
658.6	Chloroalkanes C-X
597.5	Bromoalkanes or chloroalkanes C-X
537.4	Bromoalkanes C-X

These bands indicate the presence of amine, carboxylic acid, alkynes and aromatic functional groups.

4.2.2.3. SCANNING ELECTRON MICROSCOPE (SEM):



For drug delivery biodegradable nanoparticle formulations are needed as it is the intention to transport and release the drug in order to be effective.

4.2.2.4. CHEMICAL ANALYSIS OF *JALAMANJARI CHENDOORAM*

S.NO	CHEMICALS	RESULT [+] / [–]
1.	SULPHATE	+
2.	CHLORIDE	+
3.	PHOSPHATE	+
4.	IRON	+

The chemical analysis shows the presence of anions namely phosphate, sulphate, chloride radicals enhances the osmotic regulation of the cells and its metabolism.

4.3TOXICITY STUDY RESULTS

All the animals from control and all the treated dose groups up to 100 mg/kg survived throughout the dosing period of 28 days. No signs of major or significant intoxication were observed in animals from lower dose groups. Animals from all the treated dose groups exhibited comparable body weight gain with that of controls throughout the dosing period of 28 days. Food consumption of control and treated animals was found to be comparable throughout the dosing period of 28days. Ophthalmoscopic examination, conducted prior to and at the end of dosing period on animals from control and all the treated dose groups did not reveal any abnormality.

Haematological analysis revealed no significant abnormalities attributable to the treatment. Biochemical analysis conducted at the end of the dosing period, revealed no remarkable abnormalities attributable to the treatment. Functional observation tests conducted at termination revealed no abnormalities. Urine analysis, conducted at the end of the dosing period revealed no abnormality attributable to the treatment. Organ weight data of animals sacrificed at the end of the dosing period was found to be comparable with that of respective controls. Gross pathological examination did not reveal any abnormality. Histopathological examination did not reveal any abnormality.

Conclusion

In Conclusion, no toxic effect was observed upto 50mg/kg of *Jalamanjari Chendooram* treated over a period of 28 days. So, it can be concluded that the *Jalamanjari Chendooram* can be prescribed for therapeutic use in human with the dosage recommendations of upto 50mg/kg body weight p.o.

Study of *Jalamanjari Chendooram*

Table 4.3.1: Dose finding experiment and its behavioral Signs of Toxicity

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	**500**	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	**1000**	+	+	-	+	-	+	-	+	-	-	-	-	-	-	-	-	-	+	-	+
3	**2000**	+	+	-	+	-	+	-	+	+	-	-	-	-	+	-	-	-	+	+	+

1. Alertness 2.Aggressiveness 3. Pile erection 4.Grooming 5.Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14.Analgesia 15.Lacrimation 16.Exophthalmos 17. Diarrhoea 18. Writhing 19. Respiration 20. Mortality

4.4.1DIURETIC ACTIVITY OF *JALAMANJARI CHENDOORAM* IN RATS

Neither mortality nor any gross behavioural changes were observed during and after the treatment. The *Jalamanjari Chendooram* was found to be safe up to 500 mg/kg. Frusemide treated rats showed a significant increase in volume of urine and urinary excretion of sodium, potassium and chloride ($p< 0.01$) as compared to control while *Jalamanjari Chendooram* 50mg treated rats did not show any significant increase in urine volume but has high electrolyte excretion potential ($p< 0.01$).

Jalamanjari Chendooram 50mg/kg showed remarkable increase in volume of urine, urinary sodium, potassium or chloride. Diuretics relieve pulmonary congestion and peripheral edema. These agents are useful in reducing the syndrome of volume overload, including orthopnea and paroxysmal nocturnal dyspnoea. They decrease plasma volume and subsequently venous return to the heart. This decreases cardiac workload, oxygen demand and plasma volume, thus decreasing blood pressure. Thus, diuretics play an important role in hypertensive patients.

Conclusion

On the basis of the results of present investigation, we can conclude that ash and successive *Jalamanjari Chendooram* might be good diuretics. In present study, no lethality was observed at least for the dose and duration used. However, advanced toxicological studies remain to be performed in rodents. It remains necessary to study eventual adverse effect of this *Jalamanjari Chendooram* such as alteration of some metabolic and hormonal parameters.

Table 4.4.1.1 Diuretic activity of *Jalamanjari Chendooram* in rats

Group	Treatment	Urine volume at different time intervals (in ml)				
		15 min	30 min	45 min	60 min	120 min
Control	Normal saline	0.27±0.04	0.51±0.02	1.06±0.05	1.02±0.08	1.54±0.22
Test 1	*Jalamanjari Chendooram* 25mg/kg	0.25±0.03	0.74±0.01 *	1.24±0.05	1.88±0.11	2.15±0.30
Test 2	*Jalamanjari Chendooram* 50mg/kg	0.29±0.04	0.62±0.01	1.36±0.07*	2.69±0.10	3.96±0.42**
Standard	Frusemide (20 mg/ kg)	0.34±0.05	1.46±0.1**	2.28±0.12**	3.38±0.18	4.87±0.24**

Values are mean ± SEM, * p< 0.01, ** p< 0.05 when compared to normal saline (control)

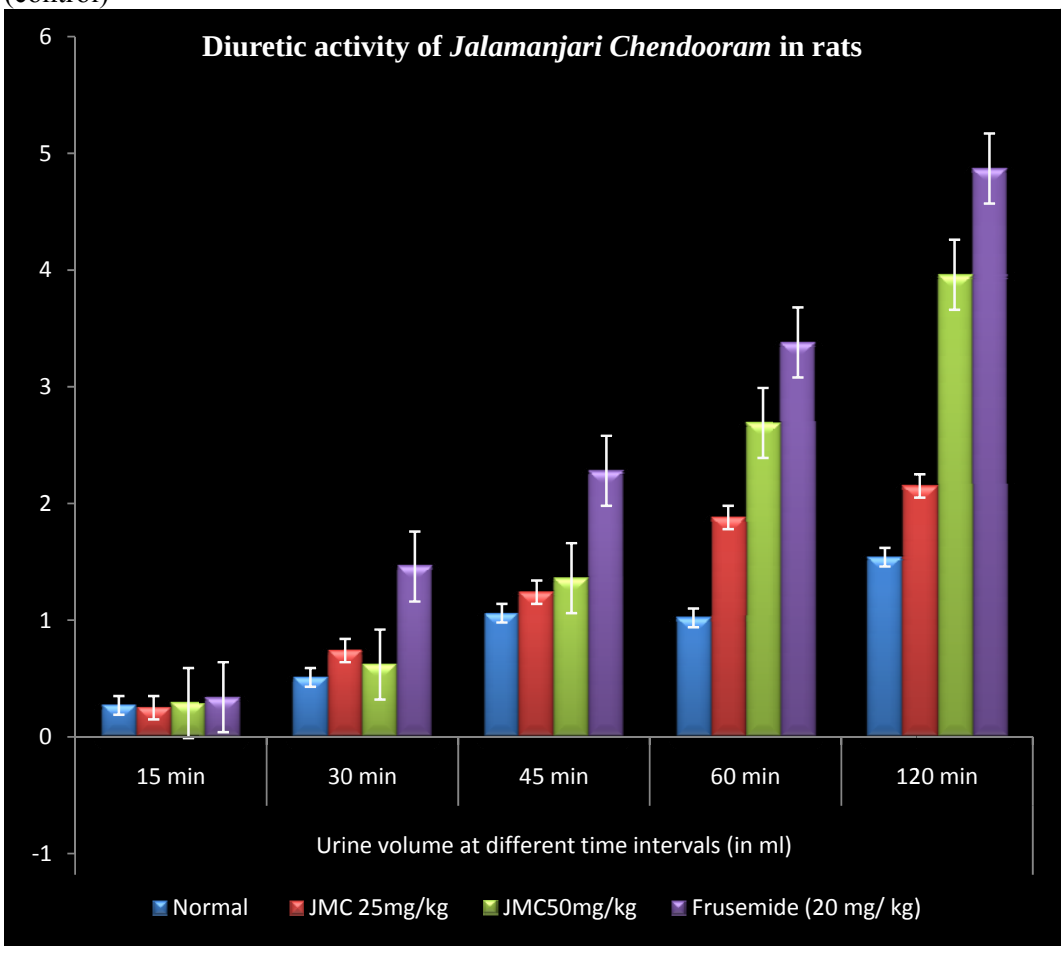
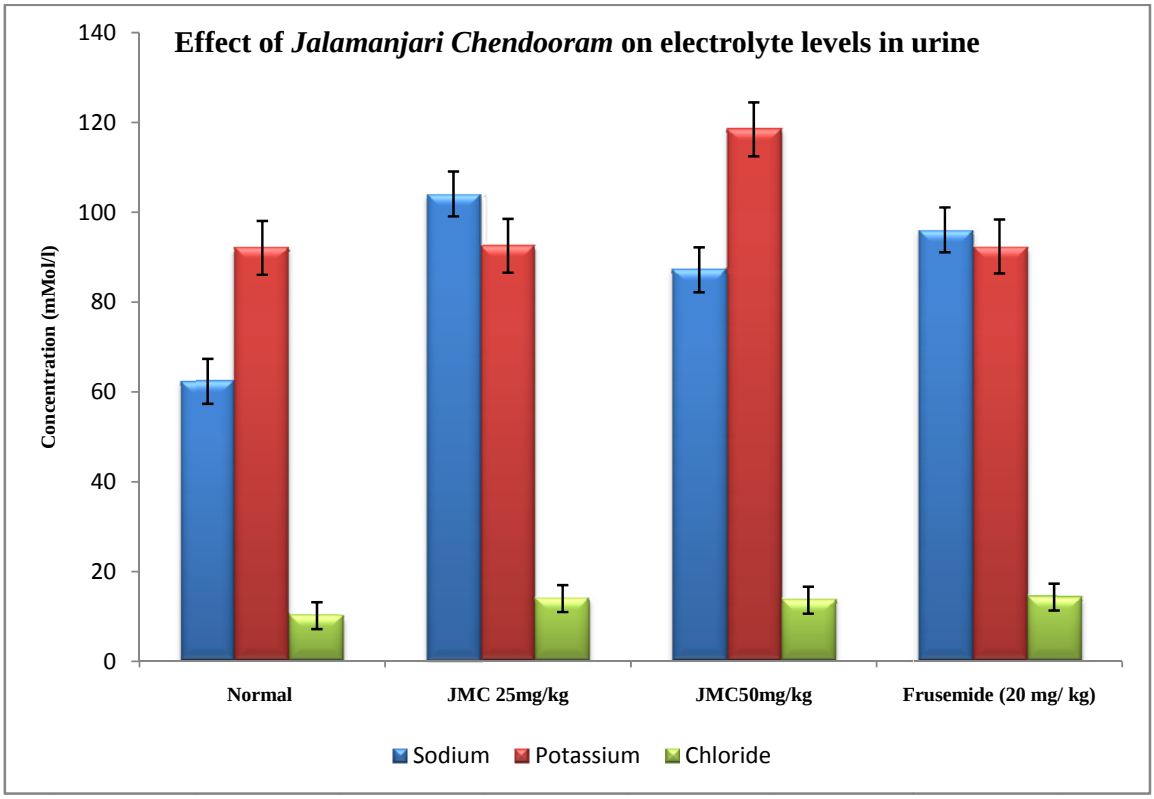


Table 4.4.1.2: Effect of *Jalamanjari Chendooram* on electrolyte levels in urine

Group	Treatment	Sodium (mMol/l)	Potassium (mMol/l)	Chloride (mMol/l)
Control	Normal saline (25 ml/ kg)	62.38±0.08	92.10±1.24	10.20±1.21
Test 1	*Jalamanjari Chendooram* 25mg/kg	104.11±0.51**	92.56±2.88	14.01±0.04
Test 2	*Jalamanjari Chendooram* 50mg/kg	87.21±1.02**	118.49±4.15**	13.65±0.80
Standard	Frusemide (20 mg/ kg)	96.10±0.66**	92.40±0.18	14.34±1.74*

Values are mean ± SEM, * p< 0.01, ** p< 0.05 when compared to normal saline (control)



4.3.2. Histopathological Features

Bone

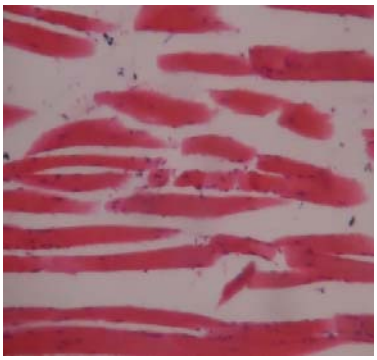


Fig. 4.3.2.1.1 Lowdose

Fig. 4.3.2.1.2 Middose

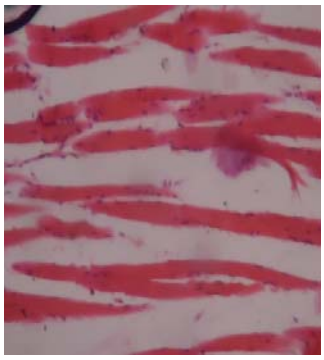


Fig. 4.3.2.1.3 Highdose

Brain

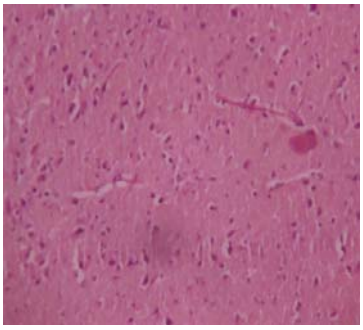


Fig. 4.3.2.2.1 Lowdose

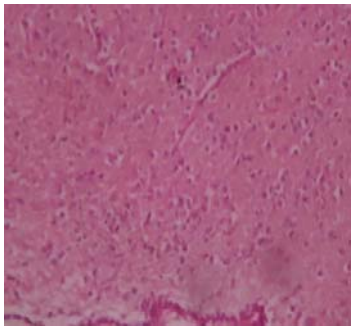


Fig. 4.3.2.2.2 Middose

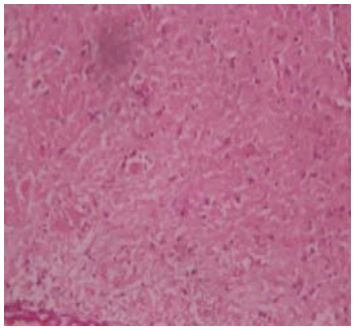


Fig. 4.3.2.2.3 Highdose

Heart

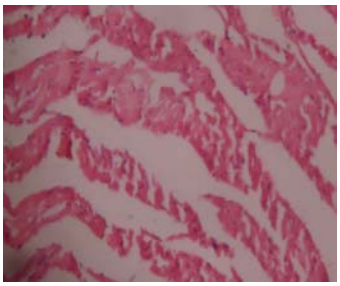


Fig. 4.3.2.3.1 Lowdose

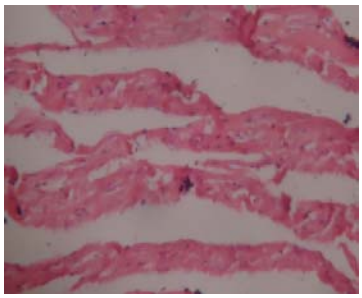


Fig. 4.3.2.3.2 Middose

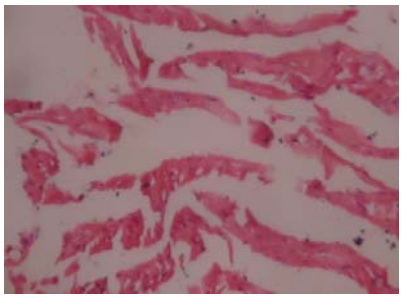


Fig. 4.3.2.3.3 Highdose

Intestine

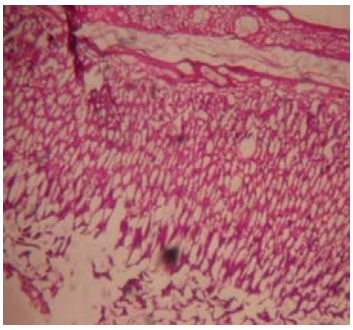


Fig. 4.3.2.4.1 Lowdose

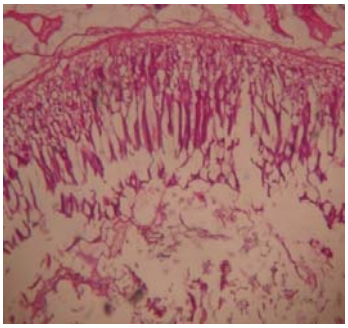


Fig. 4.3.2.4.2 Middose

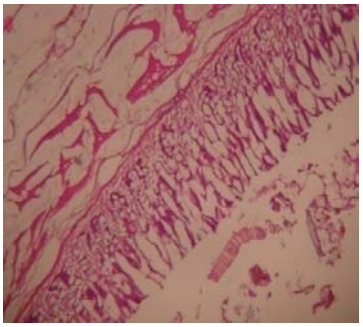


Fig. 4.3.2.4.3 Highdose

Kidney

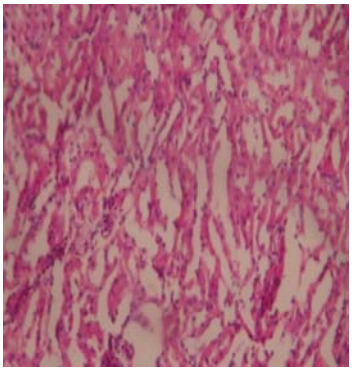


Fig. 4.3.2.5.1 Lowdose

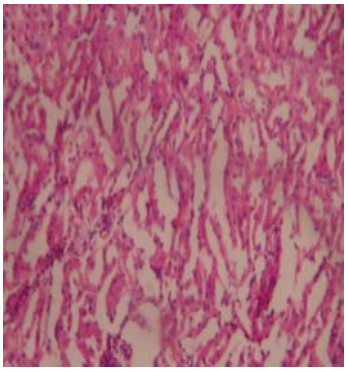


Fig. 4.3.2.5.2 Middose

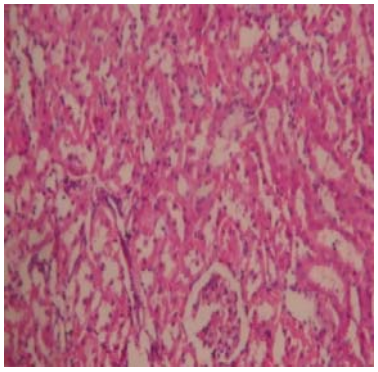


Fig. 4.3.2.5.3 Highdose

Liver

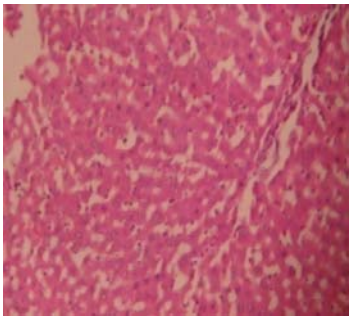
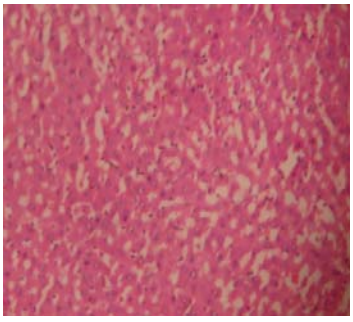


Fig. 4.3.2.6.1 Lowdose



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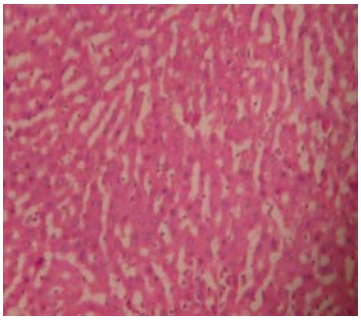


Fig. 4.3.2.6.3 Highdose

Lung

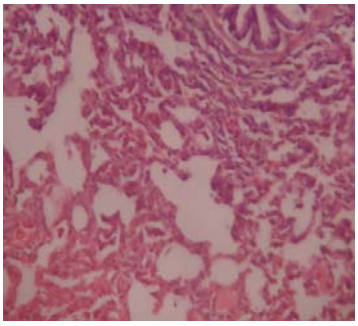
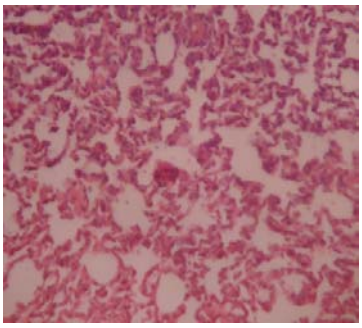


Fig. 4.3.2.7.1 Lowdose



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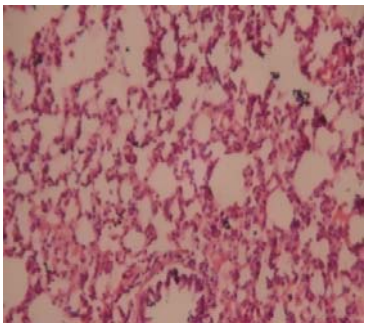


Fig. 4.3.2.7.3 Highdose

Ovary

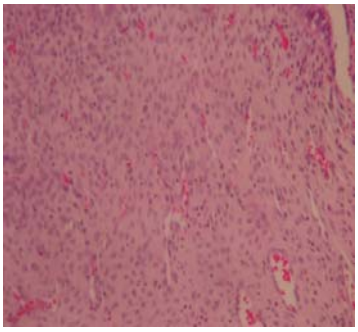


Fig. 4.3.2.8.1 Lowdose

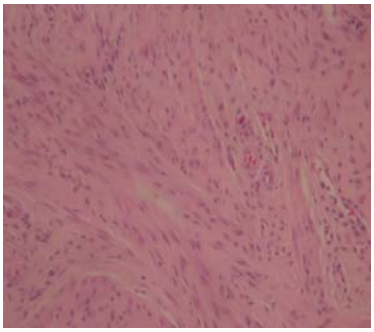


Fig. 4.3.2.8.2 Middose

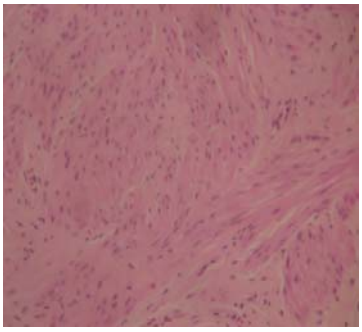
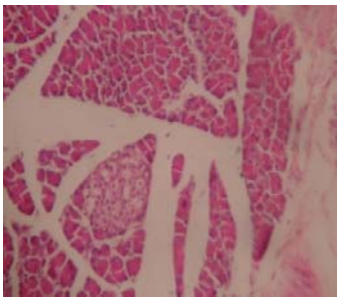


Fig. 4.3.2.8.3 Highdose

Pancreas



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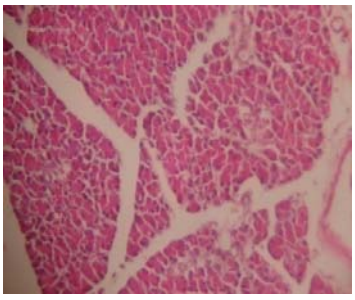

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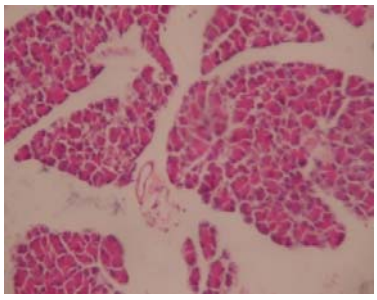


Fig. 4.3.2.9.3 Highdose

Spleen

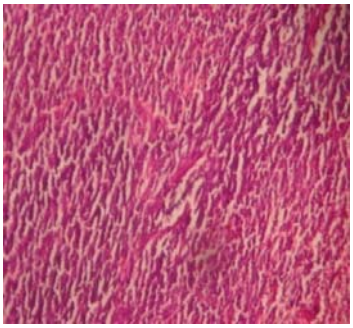
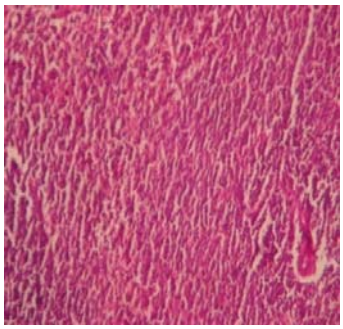


Fig.4.3.2.10.1Lowdose



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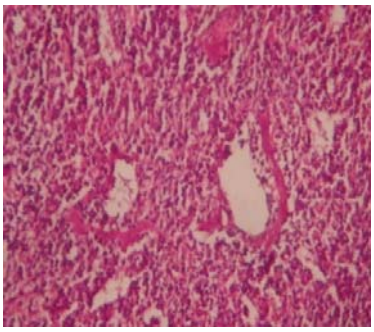


Fig. 4.3.2.10.3 Highdose

Stomach

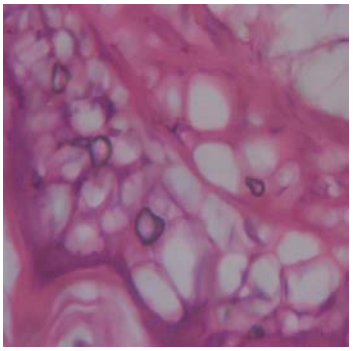


Fig.4.3.2.11.1Lowdose

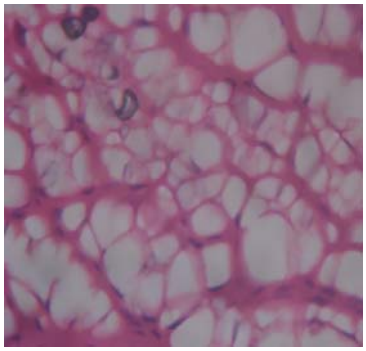


Fig. 4.3.2.11.2 Middose

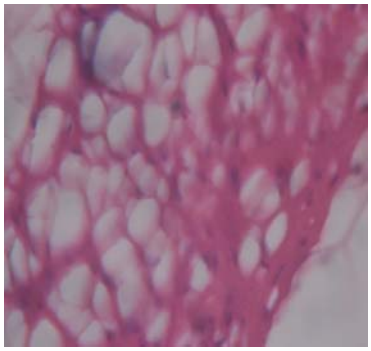


Fig. 4.3.2.11.3 Highdose

Testis

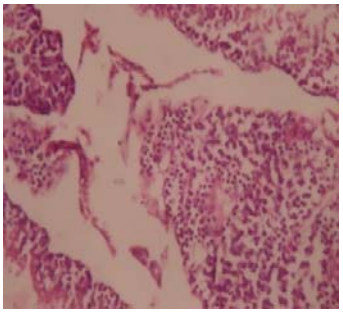


Fig.4.3.2.12.1Lowdose

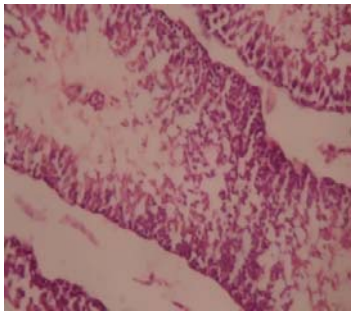


Fig. 4.3.2.12.2 Middose

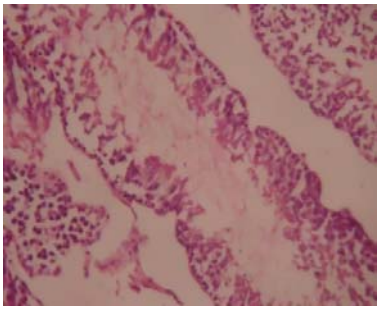


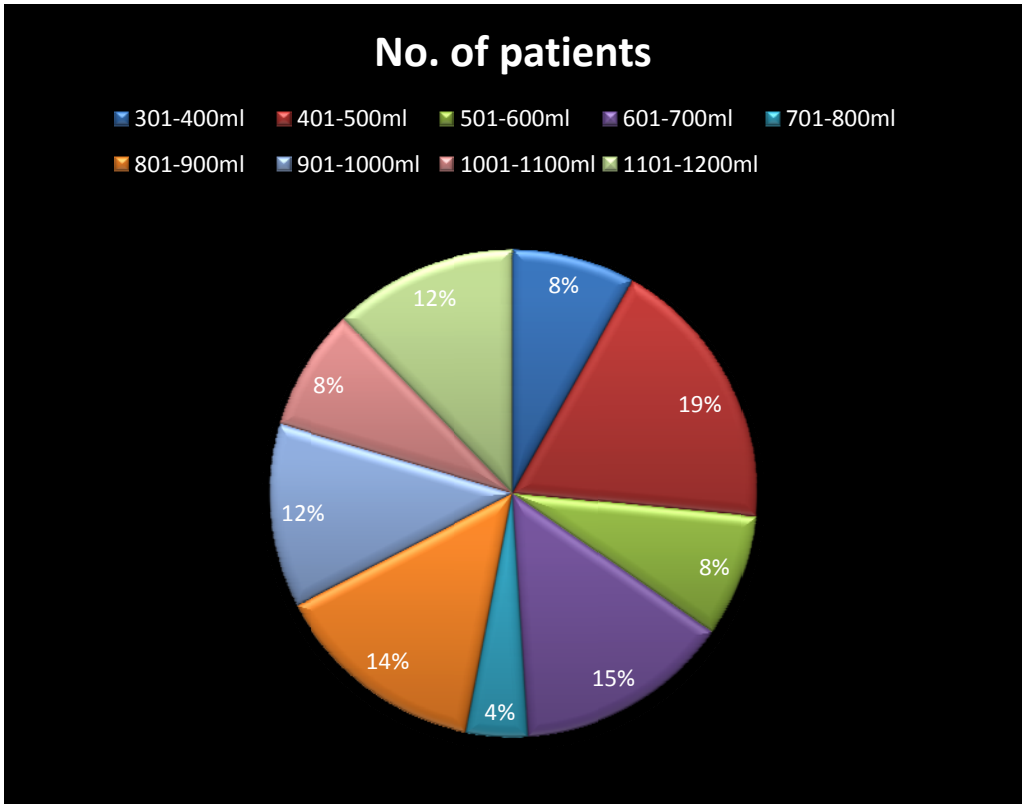
Fig. 4.3.2.12.3 Highdose

4.5. RESULTS AND DISCUSSION OF CLINICAL STUDY:

Table 4.5.10 Net increase in 24hrs urine volume

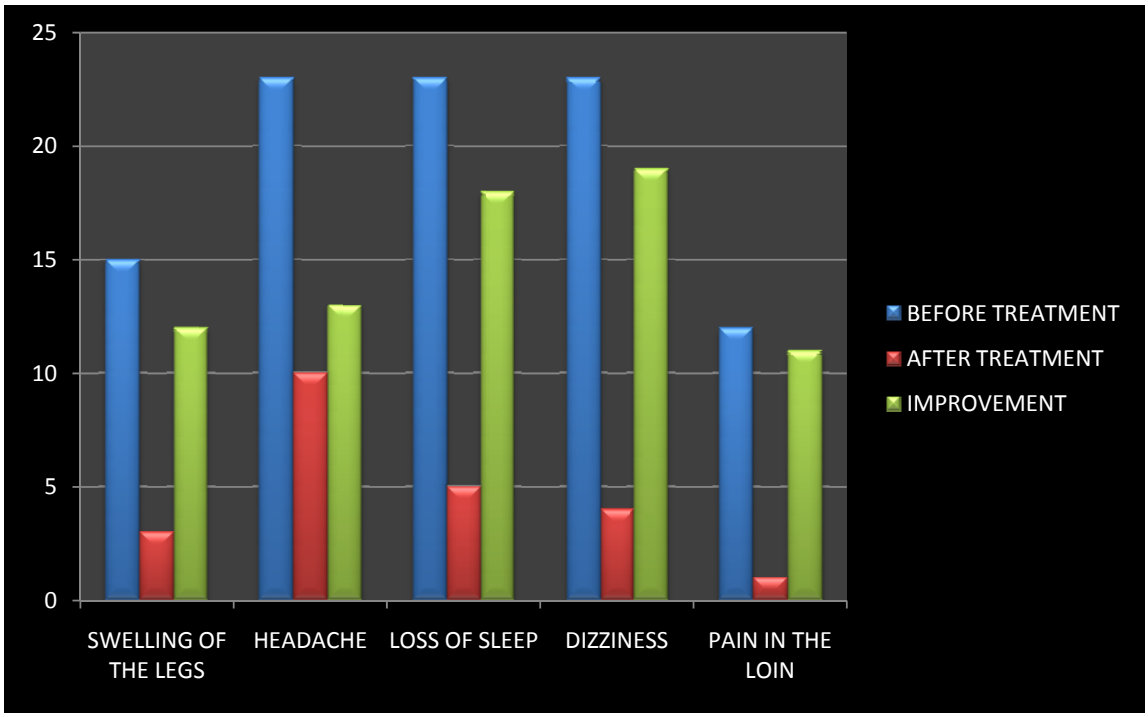
Net increase in 24hrs urine volume	No. of patients
301-400ml	4
401-500ml	9
501-600ml	4
601-700ml	7
701-800ml	2
801-900ml	7
901-1000ml	6
1001-1100ml	4
1101-1200ml	6

4.5.10. Net Increase in Urine Volume



4.5.11. Comparison of clinical features:

SYMPTOMS	BEFORE TREATMENT	AFTER TREATMENT	IMPROVEMENT	IMPROVEMENT %
SWELLING OF THE LEGS	15	3	12	80%
HEADACHE	23	10	13	56%
LOSS OF SLEEP	23	5	18	78%
DIZZINESS	23	4	19	82%
PAIN IN THE LOIN	12	1	11	92%



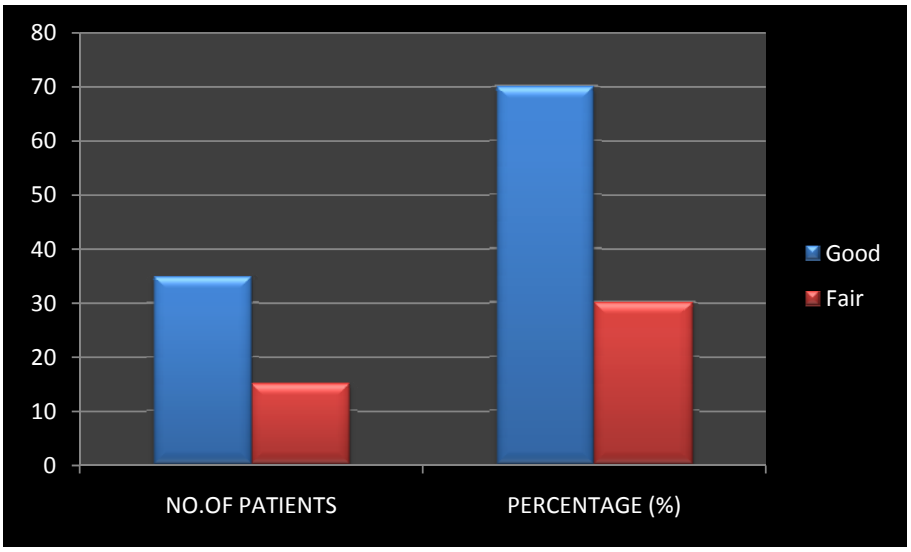
Inference:
Among 50 patients,

- 12 out of 15 patients were relieved from swelling of the legs.
- 13 out of 23 patients were relieved from headache
- 18out of 23patients were relieved from loss of sleep
- 19 out of 23 patients were relieved from dizziness.
- 11 out of 12 patients were relieved from pain in the loins.

4.5.12. Gradation of result

Sl. No	Level of improvement	No.of patients	Percentage (%)
1	Good	35	70
2	Fair	15	30
TOTAL		50	100

Results of the Patients



Clinical study:

50 patients of both sexes were selected.

Among the 50 patients, 40 patients were treated as out- patients in the Post graduate department of Gunapadam, Govt.Siddha medical college hospital and Govt. Arignar Anna hospital, Arumbakkam, Chennai- 106. 10 patients were treated as in - patients.

The patients were observed regularly.

The trial drug *Jalamanjari chendooram* was given to the patients at the dose of 200mg twice a day. Administration of *Jalamanjari chendooram* twice for 3-7 weeks resulted in significant Diuretic activity.

Out of 50 patients 4 pts excreted an increase of 301-400ml of urine per day, 9 pts excreted an increase 401 to 500ml of urine per day, 4 pts excreted an increase 501 to 600ml of urine per day, 7pts excreted an increase 601 to 700ml of urine per day,2 pts excreted an increase 700-800ml 0f urine per day, 7 pts excreted an increase 801-900ml of

urine per day 6pts excreted an increaseof 901- 1000ml,other 4 pts excreted an increase 1001-1100ml of urine per day, 6 pts excreted an increase 1100ml of urine per day.

Among 23 SHT patients, 13 out of 23 patients were relieved from headache, out of 15 oedema patients, 12 were relieved from swelling of the legs, out of 23 SHT patients 19 were relieved from dizziness, out of 23 SHT patients 18 were relieved from loss of sleep, out of 12 urolithiatic patients 11 were relieved from pain in the loins.

The results revealed that the drug possess 70% good relief, 30% fair relief.

Table 4.5.13 Statistical analysis

Descriptive statistical analysis for improvement of urine output in patients

Paired "t" test result: Table. 4.5.13A

"**p" value & statistical significance:**

Treatment	No. of patients	Mean	S.D	S.E.M
Before treatment	50	1182.3	238.1	33.67
After treatment	50	1954.18	334.92	47.85

Table. 4.5.13A showing **Paired "t" test result**

From the table we calculated the descriptive statistics like Mean, S.D & S.E.M of Mean for the improvement score before and after treatment.

"t" Table: Table 4.5.13B

t-Table	S.D	"t" Value	"p" Value
Pre vs Post	38.66	19.8697	0.0001

The two-tailed P value is less than 0.0001.By conventional criteria; this difference is considered to be extremely statistically significant.

Discussion:

The clinical study was carried out with 50 patients. Three groups of cases were studied for the diuretic effect of *Jalamanjari chendooram*, 46% Systemic Hypertension, 30% Oedema, 24% Urolithiasis patients were included in this clinical trial. The patients laboratory examination before and after the treatment, including urine volume were noted

The cumulative analysis revealed significant increase in the levels of 24 hrs urine volume. The increased urine volume levels established the diuretic effect of the trial drug *Jalamanjari chendooram.*

In the pharmacological Study *Jalamanjari Chendooram* 50mg/kg showed remarkable increase in volume of urine and in present study, no lethality was observed.

In clinical study there was a marked improvement in signs & symptoms of the patients. The results revealed that the drug possess 70% good relief, 30% fair relief. It shows the excellent safety and good efficacy of *Jalamanjari Chendooram* both in Pre clinical and clinical studies. So the trial drug *Jalamanjari Chendooram* has the potential to be used as diuretic in the treatment of various diseases.

6. CONCLUSION

Jalamanjari Chendooram is a unique type of medicine, which is made up by a special type of preparation method *erippu chendooram* in siddha system which is written by the great *Siddhar Yoogi muni* in '*Yoogi karisal 151'*.

Literature survey, Chemical analysis, Physico chemical analysis, showed the efficacy of *Jalamanjari Chendooram* as a diuretic. Since many of the constituents in the medicine according to the literature review has got a diuretic property *Jalamanjari Chendooram* is one among the gifted medicines in the siddha system. The finding of the pre clinical study suggests that *Jalamanjari Chendooram* is an effective diuretic.

Jalamanjari Chendooram had remarkable effect in increasing the 24hrs urine volume in patients before and after treatment.

In clinical trials, the drug shows the significant improvement in 70% of patients

Thus the siddha science based *Jalamanjari Chendooram* had been proved by the modern scientific parameters as an efficient diuretic.

7. SUMMARY

The poly mineral drug *Jalamanjari Chendooram* was prepared as per the traditional way. The author subjected the drug to various studies.

Jalamanjari Chendooram was selected for this study to establish the safety and efficacy of the drug as a diuretic.

The information about the drug, was collected from various text books, Literature were referred. From them, the author came to an idea about the drug and its efficacy as a diuretic.

A brief description about Siddha aspect of the minerals used in the preparation of *Jalamanjari Chendooram* characters was given.

Acute and Sub acute toxicological studies show strong evidence of the nontoxic effect of the *Jalamanjari Chendooram*. The results showed *Jalamanjari Chendooram* is safe and efficient diuretic Siddha medicine.

The pharmacological analysis showed that the drug has got significant diuretic activity.

In clinical study, the drug has showed improvement in 70% of cases.

The patients responded well from the beginning of the treatment and there were no adverse effects during the entire clinical study.

This present study suggests that *Jalamanjari Chendooram* has remarkable medicinal value as a diuretic.

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